WEST AND CENTRAL AFRICAN SMALLPOX ERADICATION/MEASLES CONTROL PROGRAM

MANUAL OF OPERATIONS

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
COMMUNICABLE DISEASE CENTER
SMALLPOX ERADICATION PROGRAM
ATLANTA, GEORGIA 30333

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This Manual is intended to serve as a guide for the development of the Smallpox Eradication/Measles Control Program in Africa. The principles set forth and procedures suggested have been developed on the basis of diverse staff and consultant experience in field epidemiology and vaccination programs in many parts of the world and on the basis of a decade of experience with vaccination and surveillance programs in the United States. However, no program has ever been undertaken of the general character and dimensions planned in West Africa. It must be recognized therefore, that this manual represents only an informed judgment regarding the principles involved and possible methods and procedures applicable to the various country programs. These require tempering in the crucible of practical field experience. In addition, each of the separate country programs necessarily will require adaptation and modification to fit the needs of the country in question, for each country has its unique administrative structure, customs and policies. The manual is printed as a "draft" rather than as a formal document. After a year's experience, a more definitive document can be prepared.

In preparing this document, full cognizance has been taken of policies and guidelines for smallpox eradication developed by the World Health Organization. We believe
there are no basic conflicts in approach or in philosophy. Because of the nature of
the assistance we are able to provide, the structure and organization of this Program,
and the early inception of the Program compared to the present timing of the global
program, the manual provides a more detailed modus operandi than has yet been developed
by WHO.

The Manual first takes up the important question of relationships of CDC staff to national authorities, other American personnel, WHO and other regional health organizations and personnel and other Program staff. Next to be dealt with, in Sections III, IV and V, are the three principal functional components of the Program: Operations, Assessment and Surveillance. Technical information pertaining to vaccines is provided under Section VI. General areas of interest with respect to field research and investigation are outlined in Section VII. General administrative procedures and procedures

relating to inventory and supply are described in Sections VIII and IX. In Section X, Reports and Records to be provided to the Regional Project Office are presented as a unit.

This material has been prepared in loose-leaf binder form to permit expansion and to allow for revisions to be made as dictated by experience.

For all concerned, we trust you will continually evaluate this manual in the light of practical field experience and that you will criticize constructively but freely and contribute regularly to appropriate revisions.

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1. To National Governments

The CDC staff are "advisors" to the respective programs. As such, they report to the Minister of Health or, more probably, and as he may designate, to some other counterpart at a lower administrative level, such as the "Chef des Grandes Endemies" the "National Director of the Smallpox Eradication Program", etc.

Specific responsibilities and relationships of the American staff may be expected to vary from country to country over a wide spectrum. In previous similar situations, CDC staff, in some instances, have been asked to assume virtually full authority and responsibility for the development and execution of the program in question; at the other extreme, they have occasionally served only in a peripheral, strictly advisory capacity. In discussions with health authorities in the various African countries concerned with this program, the point has been repeatedly stressed by African leaders that they have a very limited need for "advisors" in the strict sense of the term; instead, they need the individual who, although an advisor, can "roll up his sleeves" to participate actively in an appropriate capacity in the development and execution of the Project.

It must be emphasized, however, that whatever the relationships of CDC staff to their counterparts, responsibility for decisions and policies ultimately devolves fully and completely on the national authorities concerned. The promulgation of some policies which might appear to be unnecessary, wasteful, or even to have a harmful effect on the program are to be expected. Such policies must, however, be respected. They might even, in the light of experience, prove to be the only practical course. If policies are to be modified, the utmost in diplomacy, tact and reason will be required. Advice and assistance from the RPO, WHO advisors, AID or Embassy personnel may be helpful.

Of all facets of the relationship with national governments, the one which potentially can cause more problems than any other, if ineptly handled, is the area of press-radio-television publicity. Conversely, if these media are skillfully employed, the benefits are enormous. Requests for news interviews, pictures, etc., are to be expected. Not surprisingly, the focus of attention is frequently on the "expert from out of town". The manner in which these requests are handled is crucial. However flattering it may be to receive personal publicity, it must be kept in mind that none of the SEP personnel will be in the countries for more than a few years while national officials hold a continuing responsibility for the conduct of health programs. It is desirable, therefore, that all publicity should serve to strengthen the image of the national officials and the image of their government with the people. The spotlight thus should be focused upon them. If they request, more specifically if they insist, on the spotlight being placed occasionally on American advisors, appropriate response is indicated. It is well to keep in mind, however, that the longer term benefits of such publicity to the country itself may be limited. Cooperation with USIS in their efforts to present a favorable American image is desirable but these requests should be carefully balanced in the light of relationships with the national government. Discussion in advance with counterparts of all proposed or impending publicity to assure that they are agreeable will prevent a great deal of grief.

Parenthetically, in the past, it has been our experience, both in the United States and abroad, that more than adequate recognition will be given our contributions to any program even when every effort is made to stay "behind the scenes."

2. To WHO

A close working relationship with WHO assigned staff is of the utmost importance. WHO Country Representatives or "WR's", the WHO Inter-country Smallpox Advisor (Dr. Hans Mayer) and personnel from the Brazzaville Regional Office will all be interested and concerned with the Program. It is our hope, in fact, that Dr. Mayer might eventually be situated in Lagos to insure the maximum communication

and consultation between the RPO and WHO. Dr. Mayer and the WR's should be kept fully informed regarding the plans and progress of the Program on a concurrent basis. They, in turn, will report to the Regional WHO Office in Brazzaville and the Regional Office to Geneva.

In general, national authorities will keep the WHO staff informed. However, since the West Africa Smallpox Eradication Program is part of a global effort undertaken in concert with WHO, CDC staff should personally insure that WHO staff are fully and concurrently conversant with the program. Should the need arise to seek support for local costs or other assistance, or food from the Food for Peace Program, such continuing contact should facilitate consideration of these requests.

3. To Embassy and AID

As pointed out by Ambassador Estes, the Ambassador in each country is responsible and accountable for all U.S. government-sponsored Projects and personnel in his country. His paramount jurisdiction, as the personal representative of the President is clear. In the development of the present Project, the respective Ambassadors and their staffs have been of substantial help to us in arranging contacts and meetings with national government officials, in clarifying governmental relationships, and expediting knotty administrative procedures pertaining to visas, transport, etc. When you initially visit the Embassy or Consulate (Nigeria Regions), you should discuss the degree and frequency with which the Ambassador or members of his staff wish to be kept informed regarding the progress of the Program. As Ambassador Estes pointed out, it is possible that in some countries you will be requested to attend certain Embassy staff conferences.

Administrative relationships regarding payment of local-hire personnel, travel, provision of gasoline and maintenance for vehicles assigned personally to technical staff are still being discussed. In most countries, administrative services are provided by the same Embassy or CAMO (Combined Administrative Management Organization) staff for all of the various agencies working in the country. The only problem to be resolved relates to the question of how these costs are to be charged, a

bookkeeping operation. In Nigeria and Ghana, where separate AID administrative structures are operative, your contacts, at least for the present, will be with AID staff. A copy of the cable sent to each of the Missions explaining at least the interim handling of financial matters will be provided to you at the time of your departure.

In addition to these relationships with AID and Embassy staff, AID/Washington has advised that "AID officers will be expected to exercise the same degree of surveillance and objective evaluation regarding the measles/smallpox program as over any other AID project." It is important, therefore, that AID/country be kept informed regarding progress, plans and problems. In the development of budgets and commodity needs for succeeding fiscal years, they will, of course, be concerned. Their advice and assistance should be sought as appropriate.

For assistance in the area of health education, the USIS group may be of considerable help as they have been in the past. It is well to re-emphasize, however, that in the operational aspects of the program, the participation of the USIS should be requested only after full concurrence on the part of the national government; such publicity as may be developed must have the blessing of the national government (see previous).

4. To OCCGE and OCEAC

Both of these Regional organizations have played and are expected to play a continuing, significant role in developing and encouraging cooperative and coordinated health programs among their member nations. It is well recognized, by Africans and Americans alike, that it is difficult for the many less populous nations of Africa, working independently, to carry out effective programs in diverse areas including health. Cooperative enterprise and common policies such as are embodied in many OCCGE and OCEAC functions can result in more effective programs which are greater than the sum of the component parts. Without question, it is necessary that we do all that is possible to strengthen the fabric of these organizations.

Recognizing this, the Regional Project Office and, specifically, the medical officers assigned to Upper Volta and Cameroon have been requested to maintain close liaison with the respective organizations.

5. Among Project Staff

For each country, a medical officer has been assigned principal administrative responsibility for the SPE/MC activities. From the inception of planning, however, it was recognized that a team effort on the part of medical officers and operations officers was requisite. With limited skilled staff available in Africa, it was clear that there would be many occasions when operations officers would be engaged, for example, in field investigation or training in smallpox diagnosis while medical officers would be engaged in vehicle repair or instruction in jet gun operation and maintenance, etc. Key to the success of this program is the determination to do what is requisite to get the job done whatever one's professional training or job description.

Operations officers assigned in countries where no medical officer is in residence must be delegated sufficient authority and responsibility with respect to matters of policy and planning to permit them to operate effectively. Since communications throughout West Africa are limited at best, it would seem prudent to delegate responsibility to the maximum extent practical. The degree of delegation should be carefully defined by the responsible medical officer and, with the operations officer, he should periodically review the frame of reference. The operations officers concerned should communicate directly to the RPO in special circumstances only, for example, in case of immediate need for spare parts or other supplies. If there is direct communication with the RPO, a copy of the communication or note regarding action taken should be simultaneously sent to the responsible medical officer in order to keep him currently appraised. Monthly reports should be sent directly to the RPO with a copy to the responsible medical officer. RPO staff similarly will communicate through the responsible medical officer unless special circumstances dictate to the contrary.

The RPO represents the intermediate echelon between country assigned staff and Atlanta Headquarters for administrative, supervisory and consultative services. It has been staffed and funded to insure frequent contact on the part of RPO staff with the field. Broad administrative powers and responsibilities have been delegated to this Office. By virtue of their frequent contact with all in the field, they will be better acquainted with immediate problems than Atlanta Headquarters staff and, consequently, should be able to find more immediate and practical solutions than those at Headquarters. Only in exceptional circumstances, or by prearrangement and agreement, should contact with Atlanta be made directly by field staff.

OUTLINE OF OPERATIONS

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OUTLINE OF OPERATIONS

INTRODUCTION

The operational objective of the Smallpox Eradication/Measles Control Program in West Africa is to interrupt transmission of these two diseases, completely in the case of smallpox and in the case of measles sufficiently to reduce the disease to a level of relative insignificance. Since the target with respect to smallpox is eradication, a finite goal, and since this involves a careful systematic vaccination of all ages and segments of the population, operational procedures and techniques focus principally on smallpox vaccination. Measles control activities can readily be accomplished within this framework simply by simultaneous vaccination of young children.

Smallpox eradication will be realized by successfully reducing, through vaccination, the number of susceptibles in the West African population to the point where it is impossible for the disease to sustain itself in a continuing chain of transmission.

The extent to which the level of susceptibility must be reduced to achieve this in any area or any population group is dependent on a number of factors including population density, size of the existing disease reservoir, birth rate, migration rate, and frequency and character of disease introduction. Success will be realized through a continuing appraisal of the existing situation and adapting the attack to these conditions.

It is impossible to design a set of specific operational directives which will fit all countries or even all areas of a single country. The purpose of this section is to identify some general principles of operation which have been shown effective in accomplishing the objective of interrupting disease transmission.

In attacking disease in its natural habitat, principles must be translated into specific actions within the context of the characteristics of the population and the disease in the area. Frequently, these conditions will be poorly documented or unknown and judgments will have to be made on the basis of inadequate information. It is hoped that the principles outlined will be of use in making such judgments. However, they should not be regarded as the only means to an effective program and in some instances

may not even be the <u>best</u>. Flexibility and a sense of opportunism within a framework such as this will be necessary to an expeditious and successful conclusion.

I. BACKGROUND

The strategy and tactics of a successful smallpox campaign in Bolivia have been described by Frederiksen. This campaign resulted in complete cessation of smallpox transmission. In discussing reasons for the effectiveness of this campaign, Frederiksen lists twenty contributing factors. Some of these apply specifically to the situation in Bolivia, but 16 are immediately relevant to operations in the West African campaign:

- "Organization in administration and logistics of the campaign specifically designed to facilitate mass vaccination by mobile teams."
- "Separation of the functions of vaccination, supervision of vaccination, and inspection of results, routine analysis of statistics and epidemiologic assessment."
- 3. "Uniform methods specified in a manual of procedures."
- 4. "Job descriptions for all categories of personnel."
- 5. "Adequate provision of funds, equipment, vaccine, and transportation."
- 6. "Contractual employment of auxiliary personnel subject to professional supervision and probation."
- 7. "Merit system pay scale, allowances, uniforms, and field equipment to enhance efficiency, morale, and discipline."
- 8. "Organization of vaccinators into motorized teams and concentration of the teams in one area at a time to increase mobility, facilitate supervision, and shorten supply lines."
- 9. "Advance planning of itineraries of 3-4 weeks duration, followed by one week of rest and preparation for the next itinerary."
- 10. "Start of mass vaccination in the main streams of infection."

- 11.* "(House-to-house) vaccination of all regardless of the history of vaccination
 or smallpox, excepting only the newborn, the acutely ill, and those with
 Generalized Eczema."
- 12. "Exclusive use of lyophilized vaccine to insure potency at the time of vaccination."
- 13. "Elimination of the prior application of alcohol or other viricide to the site of vaccination."
- 14. "Use of indelible dye in lieu of vaccination certificates and cumbersome records for a more rapid, reliable control of the quantity and quality of vaccination."
- 15. "Routine inspection of sample households for evidence of quantity and quality of vaccination about nine days after vaccination."
- 16. "Health education and public information designed to reach even the illiterate."
 - * Parenthesis added West Africa to be primarily "vaccination post" oriented.

With the exception of Item No. 15, which relates to reassessment phase, the remainder of these factors bear directly on campaign operations, and may be grouped into four categories:

- 1. Organization and planning
- 2. Staffing and personnel management
- 3. Field activities
 - 4. Public relations and publicity.

Experience in Tonga, Togo, Jamaica, India, Brazil and other areas in South

America suggest that this framework is a general one applicable to mass campaigns,

irrespective of the disease target.

II. ORGANIZATION AND PLANNING

Deliberate organization and planning must precede any field activity. To be considered are the needs which have given rise to the program, the resources available in approaching the problem, and the objectives to be established.

The state of organization and planning at the *time of arrival of American personnel will vary widely among the various countries. Some will be working in already-developed programs which have been organized for some years and onto which the Smallpox Eradication/Measles Control effort is grafted. In others, organization and planning is just beginning. The degree to which planning can be affected by U.S. advisory personnel is, therefore, likely to be quite variable. Programs already in progress should be subjected to judicious scrutiny to ascertain whether the principles enumerated have been incorporated, and to estimate the degree to which these concepts are presently or could be effective in the operation. In new programs, the planning from the inception should consider these principles.

A. Collection of Pertinent Information

The existence of a country program implies that a need is felt for such an activity. This need must be documented to the degree necessary to define the scope of the problem, to appraise the resources available, and to intelligently match these resources to the problem. It is necessary, therefore, to have information regarding the overall magnitude of the smallpox and measles burden in terms of numbers of cases, age-, sex-, and area-specific patterns, the size of the population and its growth characteristics, and an enumeration of financial and staff resources which can reasonably be expected to be available. Some of this information will be immediately available; some may require more detail searching or reconnaissance surveys. Recognizing that the more adequate the information available, the better the planning, a reasonable balance must always be struck between the "educated guess" and the documented fact.

In order to establish the number of vaccinations which must be given during the attack phase, the size and distribution of the population and its rate of increase is of obvious importance. Estimations for any particular country can be undertaken in collaboration and consultation with the Regional

Project Office statistician and with WHO representatives. The best available demographic data, including population projections and vital statistics, have been included in Smallpox Surveillance Report No. 4 (October 15, 1966). Most countries will have some information regarding the numbers of live births, as well as the rates of neonatal and infant mortality which permit the estimation of the rate of population increase. Where no data are available, one may, for planning purposes, use a 4 percent annual population increase. Although this is probably somewhat high for most areas, it represents a safe estimate. Since the Program also involves the administration of measles vaccine to children, generally those five years and under, specific planning for the measles component of the campaign will necessitate an approximation of the population and population increase in this age group. A general guide for rough estimation is provided by Morley from studies in Western Nigeria. He ascertained that in a population of 100,000, approximately 4,000 births occurred each year. Based on this, he estimated that children under five years of age should constitute approximately 15 percent of the population.

B. Timing of Campaigns

Since the objective of the vaccination campaigns is to induce a high level of immunity in the population, several factors influencing this level must be considered which bear on the speed with which the overall program needs to be carried out. Although measles immunization produces a long-lasting if not lifetime immunity, it is recognized that smallpox vaccination is followed by a waning immunity, and complete protection cannot be assured longer than three years after successful vaccination. After three years, the proportion of person with full immunity falls gradually and "breakthroughs" become more frequent. In addition, susceptibles to both diseases are continually being added to the population at a rate equivalent to the birthrate minus the meanatal and infant mortality rates. Migrants, particularly in urban areas, may constitute a susceptible population group. The accumulation of such susceptibles over a three-year

period will be significant in all countries. Therefore, total geographic coverage of a country by vaccination should be completed as rapidly as possible, certainly within three years; repeat cycles of vaccination may have to continue until continental or at least Regional eradication is accomplished.

Obtaining total coverage in three years requires realistic planning.

Estimates should be made and goals set for the number of vaccinations during each year. Monthly targets for the first year will assist in early assessment of the adequacy of pre-planning and will indicate if, where, and how additional staff and/or facilities may be required to finish the vaccination cycle on schedule.

Another aspect of timing is the need for realistic scheduling of field activities during the year. It may be necessary to limit active vaccination to certain times of the year for reasons of climate (season) or the traditional customs of certain tribal peoples. Seasonal factors can readily be planned for, since, e.g. the period of heavy rains when roads are impassable is widely known and recognized as a limitation. Less evident, and often ignored in planning, are the human factors controlling accessibility to some populations. For example, the Moors of Mauritania and the Touaregs of Niger are widely scattered over a vast territory except during the period of the date harvest in August, when they may be found concentrated at certain oases; large numbers of the Fulani of Niger and Northern Nigeria leave their homelands during the dry season to drive their cattle southward when the grasslands of the north dry up; some fishing villages of the Niger delta are nearly devoid of population for several months of the year when entire family groups move to fishing grounds close to the Bight of Benin. These are but a few examples of the more extensive types of population movement. Less dramatic, but equally important for planning a vaccination campaign, are the seasonal changes in agricultural activity, related to planting, harvesting, etc., which can interfere with the

concentration of a rural population at a vaccination center. Unless the possibility of such customary changes in the way of life is considered, and information about them is requested of local informants, they may be overlooked, with disastrous effects on planned schedules.

C. Establishment of Priorities

Within the framework of total geographic coverage in two to three years, priorities must be established in the selection of target areas. As Frederiksen advised, the initial effort should parallel the "mainstreams of the disease" where possible. Data sufficient to ascertain these "mainstreams" may be inadequate. One then must rely on a general epidemiologic understanding of smallpox in assigning priorities. Dependent on person-to-person contact and on a steady availability of susceptibles, smallpox is a "crowd disease." Since the smallpox virus is dependent on person-to-person transmission for survival, it has essentially the same difficulty in reaching remote population groups as does the vaccinator. It is reasonable to assume then that incidence is directly related to density of population, and that urban concentrations represent the most fertile soil for the maintenance of transmission.

Since urban populations are most accessible, it is possible that previous vaccination efforts have been more intense in these areas than elsewhere. If so, the mainstream of infection may lie within particular subsegments of the urban area (e.g. lower socioeconomic areas). Conceivably, the principal reservoirs may lie outside of urban areas but unless evidence exists for such a conclusion, urban concentrations, in theory and in the light of previous experience, must be considered of highest priority.

In general, it is better to initiate a campaign in an operational area where success can be assured than in a more difficult area where the results may be in doubt. It will take time to develop a smoothly functioning supply system and an effective method of operations. This is best accomplished under conditions of as little stress as possible.

In some countries, the Medical Epidemiologist and the Operations Officer will be in a position to advise the host country regarding appropriate priorities for initiating campaigns. In others, political considerations may dictate strategy. In one country, for example, a vaccination campaign was begun at the ancestral home of the President. Such considerations, however, represent the realities of public health practice throughout the world.

D. Continuity of Operation

Once priorities for the campaign are assigned, there is much to be gained by planning the coverage to expand in a continuum until contiguous geographic areas are covered. When campaigns are planned for urban areas, activity should be expanded in an ever-increasing arc until the population "water shed" has been completely covered. These areas may be defined by political boundaries, geographical considerations, or areas limited strictly by population dispersion factors. Every attempt should be made in planning the timing and priorities of the Program to insure that an area once approached has been fully covered. It makes little sense to conduct a number of urban campaigns at various points in a country without providing for the adjacent, peripheral populations who frequently visit and sometimes migrate to the urban areas. Team activities in an area should be conducted in continuity such that there is a ccalescence of vaccinated areas as the campaign progresses.

E. Coordination

Where possible, activities of the various teams should be coordinated in such a way that the vaccinated areas merge and a front of coverage is gradually extended throughout the country. This approach may be expected to yield better results than isolated activities at various places by teams working entirely independently of each other.

It must be recognized, however, that this important principle may have to be compromised by local circumstances. Where already-existing field programs are conducted from multiple independent centers, and the smallpox/

measles vaccination program is being integrated into such programs, the optimum coordination may not be attainable. The patterns of distribution of antagonistic or linguistically distinct tribes, administrative considerations such as salary payment and home leave practices, etc. may require that the principles of optimal coordination between teams be tempered with reality.

Coordination between the Smallpox Eradication Program and other ongoing activities in the country should be clarified early in the planning period. The nature of smallpox eradication demands a certain pace and type of operation which may or may not permit the incorporation of other disease control activities. If it is contemplated that the smallpox/measles activities will be carried out in concert with other disease control activities, objectives and priorities will have to be worked out with particular care. Coordination of the campaigns between countries and along national boundaries is an obvious need and will be a major activity of the Regional Project Office in Lagos.

F. Mopping Up and "Fire Fighting" Activities

Assessments of vaccination coverage will undoubtedly show that some areas have not been satisfactorily covered during the initial vaccination campaign. Provisions must be made, in planning, to revaccinate in such areas to increase coverage to an acceptable level.

Furthermore, the need may occasionally arise for a rapid vaccination effort in an area to control an outbreak. In pre-planning, provision should be made for handling these situations. For completion of the attack phase on schedule, the time table drawn up for area coverage should be reasonably strictly followed. If vaccination teams are frequently forced to disrupt their activities to perform mopping up or "fire fighting" operations, great damage will be done to the orderly progress of the campaign. A sound approach would be to plan from the outset to establish a group of "standby" personnel or a "floating team" specifically for such responsibilities.

III. STAFFING AND PERSONNEL MANAGEMENT

The host countries programs will vary in the degree to which staff and operating personnel have already been recruited. Some countries will have fully staffed programs, others will be in developmental or recruiting stages. In all countries, there will be an individual serving as a national program director, who will be responsible for overall supervision of the project. It is with this "counterpart" that U.S. technicians will deal in formulating program policy. It is expected that in most countries these will be medically trained individuals.

In some instances, the program directors will be operational individuals, i.e., with active, day-to-day direct responsibility for the conduct of field operations. In others, the program director may hold an official post of responsibility but will not be operationally active. The particular relationships involved in any country should be ascertained and studied carefully. The extent to which U.S. personnel will be fully participant in programs will depend upon recognizing the existing roles of various program personnel of the host country and working with them in an atmosphere of respect and tactful recognition of the existing structure.

The guidelines developed in this section regarding local personnel policies in West Africa are general, representing administrative principles found to be sound in previous experience. Specific references cited below, e.g. Waddy², derive from experiences in the direct employ of a Ministry of Health with specific responsibilities at the policy-making level for developing, organizing, and implementing country medical field units. The role of the CDC technician is not anologous to this. Further, CDC-AID is not participating in personnel salary costs at the country level.

It is of utmost importance, therefore, that CDC personnel realize their role limitations and avoid confrontations on local administrative employment policies. The development of personal relationships between CDC personnel and Ministry officials in an atmosphere of mutual respect may provide opportunities for

encouraging the evolution of host country personnel policies in accord with the principles enumerated. However, <u>CDC personnel should always bear in mind that local personnel policies and practices remain the exclusive domain of host country authorities</u>. In this matter, our "advisory" role must remain "advisory" in the strictest sense.

A. Recruitment and Screening

The CDC advisors will have no role in the selection of senior level personnel in the host country's program and probably very little with respect to other personnel or policies pertaining to them. On occasion, they may be called upon to advise on recruitment and selection of personnel at the field operational levels such as vaccination team leaders, vaccinators, clerks, chauffeurs, recorders, assessors, secretaries, and their respective supervisors. Waddy has enumerated certain guidelines which he found useful in recruiting indigenous personnel for use in static and mobile health services in rural areas in Ghana. These included:

- "1. First and foremost, the trainee must be capable of living and working contentedly in a rural area. This implies something more than the technical knowledge of the job; understanding of and sympathy with the rural way of life is equally important.
- 2. A high standard of physical fitness as life can be hard.
- 3. A working knowledge of speaking and writing the <u>lingua Franca</u> in which official work is conducted and of mathematics to the level of working out a percentage.
- 4. Youth and intelligence."

These general principles may be amplified in the context of the West

African Smallpox Eradication/Measles Control activities:

All personnel responsible for activities involving assessment, recording, and supervision must be able to read and write, either English or French, at least to a limited extent, depending upon the area. In

addition, these personnel should be capable of adding a column of figures.

- Team leaders and team supervisors will be required to perform elementary mathematical tasks to the extent of computing a percentage.
- 3. All personnel assigned to vaccination teams and assessment teams will spend a considerable amount of their time in field activities. Motivation, willingness to work in the field and, preferably, previous experience in working in the "bush" are important considerations.
- 4. Educational requirements for selection at all levels should be low enough to permit final selection of personnel from a reservoir of candidates substantially larger than the number of personnel required. As Waddy has pointed out², "the attitude toward schooling should be to take the maximal level at which one can expect more than sufficient applicants, from whom the best can be selected. It is then advisable not to accept the occasional applicant with a higher standard. He will probably be a man of lower intelligence who has failed to get more congenial work."
- 5. Characteristics to be sought include natural intelligence ("common sense"), eagerness to work under field conditions, experience with local customs, personal integrity, stability, and perserverance.
- 6. Standardized tests, essentially independent of formal literary and language arts capabilities, are available, such as the Progressive Matrices A-E (by C. E. Raven, published by H. K. Lewis, London), to permit testing of inherent capability even when the candidate and the interviewer speak different languages.

B. Probation and Retention

All field employees should be employed initially for a probationary period of perhaps six months to one year. The privilege of releasing employees who are found unsatisfactory for field activities should be freely used to select out the less desirable before a final commitment to career

employment is made. Such a policy, if generously used, permits a simplification of initial appointment of procedures and may provide a means for dealing with problems of patronage employment.

C. Job Descriptions

Job descriptions should be drawn up before recruiting begins. Since functions and responsibilities to be assumed by recruited personnel may vary depending on the level of personnel available for employment, it may be wise to review and revise job descriptions after field activities are underway and practical experience has been gained.

D. Salary and Promotion

These items will generally be restricted to present practices within the country. Efforts should be made, however, to establish a career merit promotion and reward system based on promotion of personnel who have shown promise and willingness in field activities.

E. Consistent Pay Practices

Provisions should be made from the outset to insure that the "pay check" arrives consistently each pay period. As Waddy (1963) attests², "the whole credit system of the tropics depends on the arrival of pay by the end of the month, which does not mean the 2nd or 3rd of the next month." Nothing will destroy the efficiency of an operating program quicker than an uncertain pay policy which makes it impossible for a man to plan adequately for family and household support, as well as for personal subsistence. For example, in some programs in the past, work has had to be halted on many occasions to allow team members to travel home to receive late-arriving checks when the need was desperate.

Per diem for travel and work away from headquarters should be arranged for central level personnel. This is often neglected. Without such provision it may be financially impossible for headquarters personnel to undertake field activities necessary to the optimal supervision of the program.

F. Morale

Adequate pay as well as an efficient system of pay disbursement is the first essential. In addition, other devices to improve morale may be employed, e.g.:

- Uniforms and/or identifying insignia, badges, etc. These may incorporate elements of nationalistic pride consistent with the national scope of the program and may in turn be utilized by headquarters public relations people in publicity directed to the populace.
- 2. Formal rewards and recognition such as cash bonuses, ceremonies, letters of commendation, medals, etc., which provide "visability" to the best functioning personnel and units. Such recognition should be based on clearly defined criteria of excellence, such as greatest number of vaccinations, highest percentage of vaccination coverage, most time afield, lowest personnel turnover, rapidity of disappearance of smallpox, etc. Vagueness in recognition policies should be avoided to prevent suspicion of favoritism. It is also necessary to exercise caution to insure, for example, that quality is not sacrificed to quantity when criteria for awards are established.
- 3. Promotion. As previously noted, recognition by promotion to assignments of greater responsibility and pay is important. No system can long endure which does not recognize excellence at the field level with elevation to posts of greater prestige, greater responsibility, and greater pay.

G. Local Volunteer Personnel

In each country, available resources will necessarily limit the number of personnel who may be employed. Opportunities will arise to use local volunteer personnel to supplement the full-time team members. Such persons are generally available in every city and hamlet and may be of assistance in organizing vaccinees into lines, ascertaining age of vaccinees, assisting in the dispersion of information about the program, rounding up reluctant or

hard-to-reach persons for vaccination (as by house-to-house canvassing), in handing out vaccination certificates, swabbing arms after vaccination, and in providing assistance in setting up and dismantling vaccination posts.

Such local support is to be fully encouraged to provide a sense of overall community participation. The active participation of such community leaders as teachers, local "medical" practitioners, religious leaders, and local political figures is generally beneficial.

H. Supervision

Irrespective of the caliber of people recruited to the program, their efficient functioning will depend in major part on close and continuing supervision of all activities. Supervision will generally fall into direct and indirect categories. Direct supervision implies a "line" structure of supervisory capability. Team leaders should be directly and personally responsible for the performance of their teams. Similarly, supervisors of several teams should be directly and personally responsible for the activities of the team leaders. At all levels, the importance of supervision should be emphasized and supervisors should be encouraged to utilize fully their authorities.

In addition to this direct line supervision, assessment mechanisms will provide indirect supervision. Where independent assessment reveals that a team is not performing effectively, pressure may be brought to bear through the direct supervisory system to see that the appropriate changes are made to correct the difficulty. Care should be taken to utilize the direct supervisory system insofar as possible to obtain such corrections. "Line" authority should generally be bypassed only when it appears impossible to correct the situation through the direct supervisory structure.

It is hoped that, as an important byproduct of the Smallpox Eradication/
Measles Control Program, supervisory resources will be expanded within the
country; this can be accomplished most effectively by assigning responsibilities and providing necessary authority to fulfill these responsibilities.

I. Team Training

Once personnel are recruited for the various jobs in question, a period of training must be undertaken to provide each operating person with a thorough familiarity of his job. He should, at the end of training, be capable of efficiently performing his task, should be aware of the existing lines of authority, and should be aware of the promotion and rewards systems operative in his benefit.

Although each member of the team will generally have a specific assignment, i.e. vaccinator, recorder, driver, etc., each should be trained, and able, to perform, to the maximum extent possible, all of the multiple tasks involved in team operations. Illness, vacation leaves, individual emergencies, and unanticipated operational situations will often necessitate one worker's assuming the duties of another.

1. Orientation

Team members should be oriented to various aspects of team operation, initially by a series of lectures. Three specific items should be covered in these preparatory discussions:

- a. Administration. Personnel involved in all levels of team operation should be informed as to the existing lines of authority and responsibility. Each man should know his supervisor and those over whom he will exercise supervision. He should be thoroughly familiar with the expected benefits of acceptable and superior performance in the field and also of the punishment for poor performance.
- b. Equipment. Each team member should be made fully familiar with any piece of equipment that he is required to use. For vaccinators and

for drivers, this involves the issuance and explanation of detailed manuals for maintenance and operation of their equipment. This will only be possible however, when such personnel are literate. When they are not, the training director must be responsible for insuring that they are fully trained by properly illustrated talks. Practical tests may be given at all stages of training.

c. Required records. Each team will be required to submit certain routine records regarding the number of vaccinations performed, etc. Such records should be discussed in depth with the teams who, at the end of training, should be fully conversant with the information required and the proper means by which it is to be recorded.

In addition, those who are selected to do assessment work should have specialized training in the methods of assessment as well as the specialized survey forms with which they will have to be conversant.

If a nearby village is vaccinated as part of training for the vaccinators (see below), the same village should be used as a training ground for the assessors.

2. Drill

Following a period of orientation and individual instruction, the team should be assembled for group drill in its operations. This should be designed so that over a period of days the team acquires a semi-automatic modus operandi. These drills should cover the details of operating in the field including the logistics of setting up a campaign in an area. Establishment of a work routine should include unpacking the truck, setting up the station, policing the line of vaccinees and otherwise assuring an orderly operation, handling vaccines and equipment, maintenance and repair of jet injectors, filling in of records, and repacking the truck and leaving the area. For those personnel who will be involved in discussions with local authorities, there should be a specific drill to

assure that they know the objectives of th€ program and can fully explain the field operations of a team to a local authority.

3. Dress Rehearsal

Once the team is familiar with its responsibilities and proposed activities, and has gone through the necessary drills to acquire technical proficiency, a series of "dress rehearsal" vaccination programs should be carried out. These may be done under any of a number of circumstances, such as at a local health center or a local industry. Smaller, outlying villages may be selected as practice areas. Dress rehearsals are the best way to identify weaknesses in team performance on any given level, and provide an opportunity to make appropriate changes either in operational techniques or personnel.

4. Duration of Training

The duration of time required for the training outlined above will vary somewhat from country to country. However, it is unlikely that such training should last less than four weeks from start to finish. The better the initial orientation of the team, the more likely is it to perform its drill and dress rehearsal efficiently. Similarly, the more dress rehearsal experiences that can be arranged before the team moves into the field, the higher may be its expected proficiency in the field.

The importance of training cannot be exaggerated; it is a task which merits all the time and attention which can be devoted to it. The training period is singularly critical in producing highly motivated personnel able to carry out their jobs with maximum efficiency and enthusiasm under the rigors of field conditions.

IV. FIELD ACTIVITIES

Many countries in the West African area have existing mobile teams deriving from sleeping sickness control services and other activities. In other areas, the rural preventive health services have been structured essentially around static health facilities. In these latter areas, the mobile team structure will have to be initiated and developed.

A. Team Composition and Equipment

1. Team Personnel

While the number of vaccination teams will vary considerably from country to country, their composition, in most instances, will be similar. When both vaccines are being administered, the minimum team required will consist of three vaccinators, one recorder, and one chauffeur. A sixth individual, capable of serving as a vaccinator, would generally be highly desirable.

2. Use of Local Personnel

This has been referred to previously but deserves amplification.

Several locally recruited assistants can be effectively used to perform a number of tasks. The formation of disciplined vaccination lines from many hundreds, sometimes thousands, of milling people is a difficult task. Local police, elders, teachers, or other persons of prominence within a village can often assist, although they will need to be supervised carefully.

An individual will be required who can wipe off excess smallpox vaccine from the vaccination site, who might also dispense cotton when local bleeding occurs. Record keeping, when restricted to a simple tally by age and sex, should require the full-time activities of at least one individual. Local personnel may assist in handing out vaccination certificates. In some instances, they may be trained to operate the jet injectors, permitting trained team personnel to supervise and organize the overall activity, repair malfunctioning jet injectors, etc.

3. Equipment

The basic equipment necessary for the operation of vaccination teams in the field are presumed to be: jet injectors, measles vaccine, small-pox vaccine, diluents suitable for both, refrigerator or ice chest, iodine for cold sterilization, silver nitrate for finger dipping, cotton balls, and a bull horn. The trucks provided are quite ample to handle the necessary equipment.

4. Supply Lines

Before departing for a field "tour", team members should be fully aware of the nearest source of supplies, the requisite times required to get from any point in the projected field tour to these supplies, and the necessary procedures for procuring supplies from this depot. Where possible, field tours should be designed such that the team ends its immediate tour in reasonable proximity to the supply base in order to refurbish its supplies before proceeding onward.

B. Initiation of the National Campaign

As previously described, priorities should be assigned with respect to initial areas of vaccination to control the "mainstreams" of disease transmission. The national campaign generally should be initiated with the maximum possible pageantry and publicity to generate as much national interest as possible. In some areas, consideration should be given to the initiation of the campaign in an outlying area near a major urban center. In Amapa, Brazil, it was found that by beginning the campaign in the near periphery of the capital city, a considerable build-up of enthusiasm resulted by word of mouth publicity, which was useful in assuring a high turn-out for the campaign in the capital.

C. Approach to an Area

1. Official Contacts

When teams arrive in an area to begin work, planning sessions should be held with official governmental representatives in that region. In French-speaking countries, this is often the Chef de Circumscription, in English-speaking countries, the Chief of the County Council. Others who might be included in these sessions include the administrative staff of the local political office, a representative from the Ministry of Health or other division of the central government, the local medical officer (if there is one), the team supervisor, tribal and civic leaders. As a general rule, the more extensive the participation, the better the dissemination of information regarding the program, the greater the motivation and the more successful the campaign.

2. Local Planning

Before beginning a campaign in an area, arrangements will have to be developed regarding living accommodations for team members, storage of vaccine and supplies, organization of local publicity, and a determination of where fuel for vehicles can be obtained. Once the basic logistics are worked out, a reasonable plan can be executed to provide effective coverage of the population within the allotted time.

3. Scheduling

The number of villages or urban concentrations within a subdivision should be tabulated along with their estimated populations. In a few areas the geographic distribution of villages may be determined reasonably accurately from maps and population data available at the national level. In most areas, available maps and population data will have to be supplemented extensively from local sources and informants.

The presence and condition of local roads and communications should be noted. Realistic schedules may then be devised based on estimates of the time required for each area of coverage.

4. Selection of Vaccination Posts

These posts should be chosen on the basis of population size and proximity to smaller, less populous villages surrounding them. Natural centers of concentration should generally be used as vaccination sites, i.e., markets, schools, churches, dispensaries, and other official or traditional centers of social interest.

5. Work Plan for Vaccination Posts

Prior to initiating field activities, the team should be drilled in a regular, coordinated routine for setting up a vaccination station, including the unloading of necessary equipment, setting up of equipment, flushing guns and preparing them for use, placing records in order, and arranging the whole in such a way that there can be a smooth flow of vaccinees.

a. Post Design

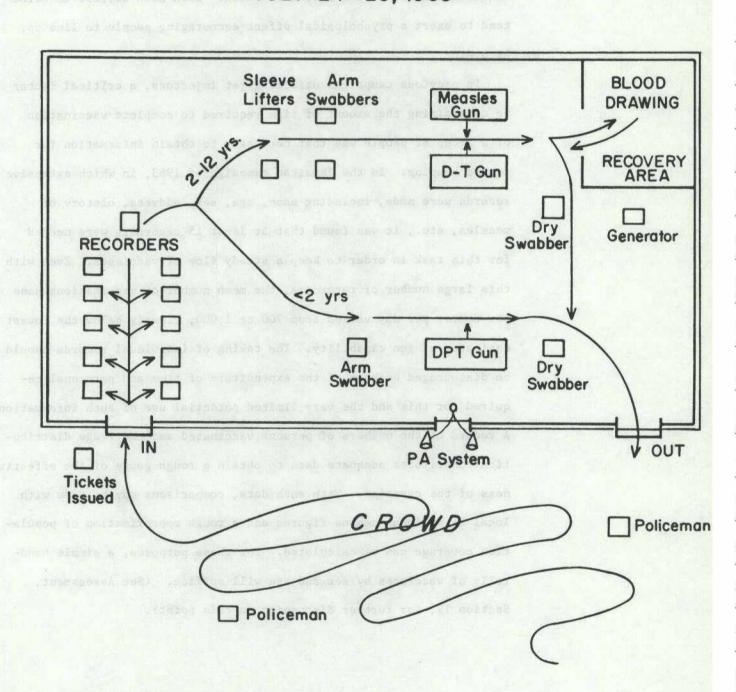
So far as possible, all efforts should be made to have the vaccinees enter at one end of a vaccination "production line" and leave at the other end, with a clear separation of those vaccinated and those waiting to be vaccinated. This is most easily accomplished by using a building with entry and exit possible only through two doors on opposite sides or ends of the building. Figure 1 is a design of a typical vaccination post utilized in the Jamaican DPT/
Measles campaign in 1963. Although this campaign required more complex record keeping, blood drawing, etc., the principles of operation were the same as those described.

The group of waiting individuals should at all costs be kept clear of the area where actual vaccinations are being performed; if not, the efficiency of the vaccinating teams will be markedly diminished. A functional setup might incorporate a vaccine tally table spaced some 15-20 yards in front of the gun operation area

Figure 1

IMMUNIZATION CENTER WINDWARD ROAD SCHOOL

JULY 24 - 25, 1963



with the line of participants extending in front of this table. There might also be a further gap of 15-20 yards between the injection area and the area where cotton, vaccination certificates, etc. are dispersed. A useful device for crowd control cited by Morley³ is the use of a simple ball of twine and a few stakes to establish a queue in front of the recorder's desk. Even such devices as twine tend to exert a psychological effect encouraging people to line up.

b. Recording

In previous campaigns utilizing jet injectors, a critical factor in determining the amount of time required to complete vaccination of a group of people was that necessary to obtain information for record keeping. In the Jamaican campaign of 1963, in which extensive records were made, including name, age, sex, address, history of measles, etc., it was found that at least 15 recorders were needed for this task in order to keep a steady flow of vaccinees. Even with this large number of recorders, the mean number of vaccinations done per center per day varied from 700 to 1,000, clearly below the lowest estimates of gun capability. The taking of individual records should be discouraged because of the expenditure of time and personnel required for this and the very limited potential use of such information. A record of the numbers of persons vaccinated and their age distribution constitutes adequate data to obtain a rough gauge of the effectiveness of the campaign. With such data, comparisons may be made with local or national census figures and a rough approximation of population coverage can be calculated. For these purposes, a simple handtally of vaccinees by sex and age will suffice. (See Assessment, Section IV, for further discussion on this point).

It is recognized that in some areas where Smallpox Eradication/
Measles Control activities will be carried out by presently operating
mobile health services teams, more extensive records will be completed
in accordance with present practices and needs. When extensive records
are necessary, the availability of persons in the village who can read
or write the lingua franca of the country might be ascertained and,
if necessary, pressed into duty as is necessary to keep a reasonable
flow of vaccinees.

Screening for Contraindications

Since contraindications to vaccination in endemic areas are few,
the recorder, through a rapid visual assessment, could exclude persons
with frank leprosy or gross generalized eczema, usual contraindications to vaccination except during frank epidemic situations. (For
a further discussion of contraindications, see section on Smallpox
Vaccines.)

Finger Dipping

In at least some countries, finger marking with silver nitrate solution will be used to provide a marker for subsequent program activities. A container of silver nitrate should be placed on or near the recording desk so as to be readily available to the vaccinee as he passes the recorder's desk. In order to standardize the technique, the left little finger should be used in all instances.

ad bloods danse e. Injection de ac mossos

As previously described, the areas where injections will be performed should be well separated from those where people are waiting
for or have completed vaccination. Under present plans, a single
vaccination area should be sufficient. This should be constituted
as a sort of corridor with the measles vaccine injector on one side
and the smallpox vaccine injector on the other. Persons of all ages

and sexes may form a single line, children in the measles age group
will receive two injections, one in each arm, and older persons will
receive only the smallpox injection. This method is much simpler
than creating two such areas and requiring the separation of children
from their parents or older siblings and their later reassembly.
Under a two-line system, the lines may be expected to move at somewhat different rates, and matching the right child with the right
parent after vaccination is likely to contribute to confusion.

The need for keeping the vaccinators free of the press of crowds cannot be underestimated. A certain rhythm is established in jet injection vaccination which results in a rapid, orderly completion of the job. A curious, noisy, pushing multitude is guaranteed to reduce efficiency.

f. Post-vaccination Swabbing

Following intradermal injection there is frequently a residue of vaccine remaining on the skin surface which may run down the arm and after intradermal and particularly subcutaneous injection, there may be some temporary bleeding at the site of inoculation. Bleeding is of little consequence except that it is occasionally alarming to the vaccinee, but a residua of smallpox vaccine on the skin surface is undesirable because of the possibility of autoinoculation or spread of virus to others and to the environment in general.

For these reasons, cotton or other absorbent material should be part of the routine supplies of an operating field team. A local volunteer can be assigned the task of swabbing the vaccination sites and dispensing cotton to vaccinees as indicated. The same individual may be charged with the responsibility of handing out vaccination certificates or whatever additional material, if any, is to be distributed by the team.

D. Team Accountability

Each team will have a quantity of equipment and material for which it must assume responsibility. Its accountability for these supplies should be clearly described.

1. Equipment

In general, the team leader should be held personally accountable for maintenance and repair of jet injector equipment, trucks, bull horns, and other non-expendable items assigned to the team. He may delegate responsibility for maintenance and repair of these items to other members of the team, as necessary, but it should be clearly understood that final responsibility for these items is his alone. It is desirable that he be provided a storage cabinet with lock (such as provided on the new vehicles) for these supplies.

2. Spare parts

The team leader should also be accountable for spare parts (for jet injectors, vehicles, and other equipment) assigned to the team. He should record the issuance of these materials, including date and reasons.

3. Vaccine

Vaccines, perhaps more than any other item available to the field teams, could be subject to petty theft. To avoid this possibility, the lot numbers of all vaccines used should be noted on vaccinee tally records for the days on which they are used. In addition, vaccine bottles should be retained after use and returned to the local storage depot from which the team draws its supplies. This will provide a cross-check between numbers of bottles used and recorded numbers of vaccinations performed. The return of empty vaccine bottles also prevents their being refilled with water or other liquids and subsequently being sold to unsuspecting victims. Such unscrupulous behavior has occurred with empty penicillin bottles in other programs.

V. PUBLIC RELATIONS AND PUBLICITY

Since the purpose of the mass vaccination campaign is to vaccinate as many people as possible when the teams visit scheduled areas, the maximum possible mobilization of the public is necessary. It is therefore necessary that the public be as well informed as possible. This is particularly key in a campaign which depends upon persons coming to vaccination centers instead of the more traditional door-to-door program with the vaccinator going to the vaccinee. There may be important byproducts of effective educational and publicity efforts, such as the improvement of the general health knowledge of the public at large, but it should never be forgotten that the primary objective is to inform people of the existence of the campaign and to interest them sufficiently to insure that they present themselves for vaccination.

With this general purpose in mind, a wide variety of publicity techniques may be used, including some not often employed in public health programs. In the past, official American public health agencies have usually restricted their "educational" campaigns to traditional conservative, low-key activities in a social environment of "hard-sell" advertising by commercial organizations; they have failed to attract the eye and ear of the public. Many feel, therefore, that public health propaganda methods require reexamination, and imaginative adaptation to the accepted norms of the society that is to be influenced within reasonable limits of professional dignity. This is not to say that the "no-holds-barred" approach of American advertising gimmickry should or can be introduced into West Africa for promoting smallpox and measles vaccination (or even that it would be effective), but rather that we approach the need for an effective promotional effort with open minds, unrestricted by the limited concepts with which we are acquainted from usual public health practice, being prepared to exploit every route, however novel, to the eyes, ears, and minds of our potential "customers." The only limitation should be, on the one hand, acceptability and effectiveness in the West African cultures, and, on the other hand, reasonable caution that long range goals in public health education are not sacrificed to single-shot attacks on the public's attention.

Methods of publicity generally fall into three categories:

A. General Information through Mass Media

These include the generally recognized mass media of television, radio, press, and other publications. They may have national and/or local scope, depending on the particular agencies responsible for such activities. These resources should be utilized to the greatest extent possible, and to this end the national SPE/MC program should establish close working relations with mass media representatives serving the country. There should be a steady bombardment of the general population with information about the program, its importance, the impact of its activities on the development of the country, etc. A feeling of national pride should be stimulated. This program, reaching as it will almost every family, should receive considerable political support, from both the central government and locally elected officials. Such support should be actively solicited and efforts made to include appropriate governmental figures in all publicity.

Another idea which has been found useful in other programs is the coining of a slogan which will be recognized throughout the country. The slogan may be used in many ways in publicity materials, may serve to identify operational field personnel, and may provide a unifying thread connecting all central and local publicity efforts.

B. Involvement of the Local Community

In West Africa, mass communications media will affect only a small proportion of the people. Most information is obtained, most advice is sought, and most influence is effected at the local level. Therefore, most of our publicity effort will need to be exerted at the local level. The variety of approaches possible is almost limitless, and only some of the more obvious, more generally applicable can be suggested here. One point to remember always, however, in

planning local publicity, is that no complete generalizations can be made not only does each community differ from every other, as we understand such
individual differences in the American context, but geographical, tribal,
religious and other social and economic factors in Africa have resulted in
cultures responsive to totally different influences. No simple approach is
possible throughout the West African area or even throughout any one country.

1. Local Leadership

The influential persons in every area and every village must be identified and their support attained. In Northern Nigeria, for example, the support of the Emirs is crucial. From them, two channels of information and support might pass - one through the hierarchy of chiefs down to the smallest village, and the other through the religious hierarchy of mullahs down to the villages and city quarters.

Influential persons in other communities may be persons of many kinds: traditional tribal chiefs; political leaders or representatives in the cities, and often in rural areas also; religious leaders, both expatriate and indigenous, and representing many varieties of pagan, Moslem, and Christian creeds; school teachers; leaders in commerce-ranging from the directors of modern business to the dominant figures among the market women; representatives of government, in administrative and technical capacities; union leaders; medical leaders - practitioners of both western and indigenous medicine, and including midwives and the like; etc. etc.

Local leadership may be obvious or may be difficult for an outsider to identify; the assistance of intelligent local informants is often necessary in order to locate them. It is always necessary to exercise caution when seeking the help of local leaders, and to bear in mind the importance of prestige, the competition of representing different community activities, and the danger inherent in the refusal of a request for support. Usually it is safest to obtain a realistic estimate of the likelihood of agreement before requesting assistance; the refusal of a

prominent individual to support the vaccination program may be interpreted as opposition, and may result in the refusal by other potential allies of the program.

2. Local Organizations

In every country, and in almost every major locality, there are organized groups eager to render assistance or susceptible to recruitment for many "worthwhile cause." These include: churches, men's and women's social clubs, Boy and Girl Scouts or their equivalent, unions, Red Cross societies, agricultural or trade societies, the police, the Army, etc.

In many instances, the support of such organizations may go well beyond their mere publicity value in "spreading the good word." They may also wish to provide volunteers to assist in team operations, to prepare promotional materials, or to help to mobilize the public by door-to-door roundup. In Ibadan, Nigeria, the entire city has been organized into a vast system of civic-minded block wardens to promote improvements in sanitation, and these prople provided massive assistance in a locally-inspired smallpox vaccination campaign several years ago.

3. Public Meetings

Where possible, convening of public meetings in the open, designed to attract large numbers of people for one reason or another, are helpful in a campaign. In Jamaica, such meetings were structured around attempts by the Federal Government to provide an educational lecture; this was followed by a brief exhortation in support of the campaign. These were found to be most effective when accompanied by movies or slides, related and unrelated to health or medical subjects. These meetings are most effective if held immediately prior to the initiation of vaccination efforts in a particular locality.

Another frequently used mechanism for gathering people is a parade. It may often be possible to arrange for a military band to pass through the streets of a city, accompanied by advertising for the vaccination campaign on hand-carried placards or motorized floats, and ending with spirited rally. Many such opportunities will be available if looked for.

It is important, however, not to overestimate the returns from such high-impact affairs as movie shows, parades, music festivals, etc. In India, these always resulted in very enthusiastic turnouts, but had little noticeable effect on vaccination coverage. There may be vast cultural differences in the effect that shows of this sort have on influencing people to engage in an unrelated activity. It may be wise to experiment with such techniques, to determine their values, before investing too much effort and money.

4. Sound Equipment

Each team will be provided with a bull horn public address system.

This device, if used with the team trucks, can produce fairly broad local impact in a short time. Again, the technique which was found useful in Jamaica was to tour the streets, providing a considerable amount of chatter on various items of local interest, with announcements of the campaign interspersed.

5. "Bush Telegraph"

This term is used to describe the effective word of mouth transfer of information which occurs in many rural areas. In Africa, this is particularly facilitated by the existence of drum communications between villages.

C. Campaign Gimmickry

This sector of public relations involves specific items developed to popularize a campaign, employing techniques which are not generally utilized

in public health communications. The spectrum of possibilities is virtually endless and will depend upon local conditions, customs, and a considerable dose of imagination. A few ideas are presented:

1. Campaign Kickoffs - Parades, Fiestas, Athletic Events, etc.

In designing a campaign kickoff, key central and local governmental personnel should be actively involved. These programs generally should take the shape of a flashy, exciting activity of one sort or another designed to attract as much attention as possible followed by the dispersal of information about the campaign and its objective.

2. Use of Local Holidays, Fairs, Market Days, etc.

An appraisal of the local situation will result in identification of specific events of local interest which may be capitalized on for the spread of information and to perform actual vaccination.

3. Raffles

In the Jamaican campaign, a radio-TV raffle was conducted. Each person presenting himself at a vaccination center was given a doubly-numbered theater ticket, half of which was retained in a box at the vaccination center, and the other half retained by the individual.

Prizes were subsequently awarded based on a drawing from the ticket stubs. Such an approach has a tendency to encourage full family participation in a program, as such increases the probabilities of a win. In some parts of Africa, also, the lottery is a popular local custom. The objects selected for any raffle will, of course, depend on local custom; donations from local merchants may frequently be obtained.

4. Prizes

In an urban area, appeal can be made to certain commercial interests to provide prizes for distribution during the vaccination campaign.

These may be distributed on any basis, e.g., "every nth person" receives a prize. The most popular items have included infant food and other

commodities which are immediately usable. In Tonga, small toy "crickets" were given away and, while having certain disadvantages in the din created, were found to be a considerable attraction to the children involved. In approaching commercial interests regarding prizes or other participation in campaigns, it should be pointed out that any effort reaching the total national population involves a remarkably broad public contact with rather important advertising possibilities.

5. Special Music

During the Jamaica campaign, a special immunization calypso was written and recorded by one of Jamaica's leading folk-artists. This was done as an entirely non-commercial effort to encourage local support in the program and was thought to be highly successful. Similar musical contributions have been made in other areas, for instance the "dengue" record which was produced in Puerto Rico during an epidemic of that disease.

These represent a few ideas which have been used in previous campaigns.

The spectrum of ideas is broad. The key to success in public relations is a wide-open approach embracing almost anything that will attract attention in a manner acceptable to the sensitivities of the general public and the leadership of the population concerned.

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ASSESSMENT

INTRODUCTION

B. TECHNIQUES IN ASSESSMENT

1. Tabulation of Vaccinations Performed

- a. Introduction
- b. Purpose of Vaccinee Tabulation
- c. General Requirements for Tabulation of Vaccinees
- d. Possible Procedures for Instituting Proposed Tally and Summary Sheets
- e. Summary for Measles Vaccinations
- f. Deficiencies in Tally Data for Assessment Purposes
- Household and Village Registers
 Challenge Vaccination
- 4. Serological Surveys
- 5. Sample Surveys by Special Assessment Teams
 - a. Introduction and General Considerations
 - b. Principles of Operation for Assessment Surveys
 - - Assessment teams
 Markers for vaccinees
 Areas for survey

 - 4) Time of survey
 - 5) Sampling method
 - a) Prior use of sampling techniques in Africab) The household as the unit of enumeration

 - c) Sample size

 - Villages and towns under 5000 population
 Towns and cities of 5000 to 100,000 population
 - (3) Cities over 100,000 population
 - (4) Villages and towns with no readily separable housing units
 - (5) Overall survey of a rural area

d) Assessment forms

- 6. Vaccination Scar Survey
- 7. Terminal Assessment

Annex I - Estimation of Sample Size

- A. For Vaccination Coverage
- B. For Vaccination Take Rates

Annex II - Variances and Significance Tests

Annex III- Table of Random Numbers

Annex IV - UN Statistical Experts in West Africa

Figure 1 - Vaccination Tally Sheet Figure 2 - Vaccination Summary Sheet

Figure 3 - Monthly Vaccination Report for RPO
Figure 4 - Sample Survey Form for Towns and Villages less than 5000 Population
Figure 5 - Sample Survey Form for Towns and Villages 5000-100,000 Population

References

A. INTRODUCTION

Assessment is a principle functional component of an eradication program.

From experience gained in several eradication efforts, it is abundantly clear that thorough appraisal by independent assessment teams of such factors as the extent of vaccination coverage in an area and the percentage of vaccine "takes" in the field is of vital importance. The effectiveness of the program can be most accurately determined on a concurrent basis and its success more certainly assured. Based on the data obtained, appropriate steps can be taken to alter current techniques and/or the tactics of the vaccination scheme.

The use of trained, independent assessment teams not involved in day to day vaccination provides greater certainty of assuring objectively gathered data of reasonable accuracy. Knowledge on the part of the vaccination teams that their work is constantly being checked, and perhaps compared, with the work of other teams, serves a motivating function and, indirectly, a disciplinary role.

Although, as will be described, assessment mechanisms of different types can be employed, the work of independent assessment teams constitutes the key component of this activity. For maximum efficiency of these teams, some type of "sampling" technique is requisite in order that the work of several vaccination teams can be appraised by one assessment group. A sampling technique believed applicable in Africa is presented as part of this section. In addition, various principles applicable to assessment procedures are discussed and specific techniques are outlined. It is to be noted that sampling procedures employed in the concurrent assessment of programs may also be used to appraise the prevalence of smallpox in an area (by survey of pock-marked individuals), the vaccination status of particular groups of concern, such as nomads, migratory groups, lower socio-economic populations in urban areas, etc., and for terminal assessment.

The assessment scheme based on cluster sampling, which is described in this section of the manual, will specify sample sizes and methods of selecting sample

villages and/or sample households in villages, towns and cities of different populations. For those readers who have interest in the formulas used to determine sample size and reliability of the sample results, Annex I and Annex II have been prepared and included as part of this section to the manual.

B. TECHNIQUES IN ASSESSMENT

1. Tabulation of Vaccinations Performed

a. Introduction

Data obtained from tally sheets at a vaccination site regarding numbers of vaccinations performed by age and sex may be considered to be the simplest and crudest form of assessment. Having made some estimate of the "target population" to be vaccinated, the team, while still at the site, can determine the approximate extent of coverage. It can also ascertain whether there is a deficiency in representation of one group or another, e.g. schoolchildren, adult males who may be working in the fields, adult females who may be engaged in marketing activities, etc. While still at the site, special efforts can be made to reach what appear to be deficiently represented groups.

Several of the African countries in this Project will have procedures already established for this type of tabulation. It is hoped that most of the data regarding vaccinations which are required for effective Regional coordination of the Project may be available through established procedures or through appropriate adaptation. It is believed, however, that in most countries use of a single tally sheet such as described below for recording vaccinees will prove useful and practicable throughout the Project area. A sample form has been devised (Figure 1) based on the experience of CDC staff who have served as advisors to vaccination programs in many parts of the United States and other areas of the world. Recognizing that exact ages are not commonly known (See Manual Appendix I), the age groupings have purposefully been kept broad to facilitate easy

recording but retaining those age categories which will be helpful in identifying pre-school children, school-age children, working adults and older adults.

b. Purpose of Vaccinee Tabulation

- 1) To determine the work output of individual teams.
- 2) To provide working teams with rough estimates of coverage obtained relative to the "target population" for a given site or area.
- 3) To determine approximate coverage, and shortfall, in specific age-sex population segments.
- 4) To provide responsible authorities, i.e. team supervisor, country and regional offices, with a continuous monitoring of team output with respect to vaccinations performed.
- 5) To provide team production estimates essential for sound logistical planning.

c. General Requirements for Tabulation of Vaccinees

Since recorders may have only a limited education, a simple method of tabulation must be employed. These methods should be standard throughout a country and, preferably, throughout the Region, at least to the extent that summary data may be derived. Because vaccination rates with jet injection equipment may approach 600 per hour, recording of age group and sex, for example, must be equally rapid.

d. Possible Procedures for Instituting Proposed Tally and Summary Sheets

1) Training. All members of the vaccination team should be instructed in the reasons for and methods of tabulation of vaccinees. The team leader should select a recorder for each vaccination team who should receive more specific training. The recorders should have sufficient education to be able to identify numbers and to add a column of figures (and perhaps to perform simple division).

2) Operations. The recorder should be responsible for keeping the team log, using uniform tally sheets and weekly summary sheets (See figures 1 and 2*). At each vaccination site he should set up the recording station in the vaccination line, fill out identifying data on log sheets, and mark the appropriate age-sex box for each person passing through the line.

As a person passes the recorder's table, the recorder or local interpreter should determine the age and sex of each subject by questioning or estimation. He should then draw a mark in pencil through the lowest number in the top line of the appropriate age-sex grouping. When 20 is reached in any line, the next number to be marked is 1 in the next lower line. As soon as any age-sex group box is filled, the recorder should use a new tally sheet and record all further vaccinations on the new sheet. At the end of the day or at the completion of work at any vaccination site, whichever is first, the recorder should tabulate the vaccinees by age-sex groupings and enter the totals in ths summary box at the lower right hand corner of the tally sheet. The summary data from each tally sheet can then be transferred to the Vaccination Summary Sheet (figure 2). When this is completed the recorder should sign his name at the bottom of the tally sheet and present the log book to the team leader. The team leader should check the summary sheet, sign it in the appropriate space, and give or send it to his superior, e.g. the supervisor for several teams. The team leader should count the number of vials of vaccine used each week and enter this figure in the weekly summary sheet. This provides a further check on the number of vaccinations performed and/or wastage or other loss of vaccine.

^{*} Tally forms such as these may have to be modified to suit individual country needs. The identifying data will usually be different, but the recording of work performed should remain the same.

The team supervisor should check and sign the summary sheets, record the vaccinations performed on a working map and send the summary
sheets at appropriate intervals, perhaps every 2 to 4 weeks, to the
country headquarters.

The country headquarters should summarize vaccinations performed

by province and age-sex groupings and include these data in the monthly

vaccination report (figure 3) sent to the Regional Project Office.

e. Summary for Measles Vaccinations

It is anticipated that most countries will vaccinate against smallpox and measles in the same operation. The proposed tally system is adaptable to the simultaneous recording and reporting of both measles and smallpox vaccinations. If measles vaccine is administered to all children through 4 years of age only, the number of measles vaccinations given would be represented by the number recorded in this age group. If the age group to be given measles vaccine differs from this, for example, including children 6 months through 5 years, the first category would have to be modified to include only infants 0 through 5 months of age and the second category to include children from 6 months of age through 4 years of age. The third category would be adjusted so that the first two lines of the 5-14 age group represents 5 year olds only and the remaining lines include the children from 6 through 14 years of age. The total of measles vaccinations performed would then be represented by all vaccinees in the second category, 6 months through 4 years of age, plus the first two lines of the third category which would consist of 5 year olds only.

f. Deficiencies in "Tally Data" for Assessment Purposes

It must be appreciated that the tally data provides little reliable information as to the actual proportion of the population vaccinated.

Although the numbers of vaccinations performed may be compared with census data or other population estimates to obtain an approximation of coverage,

such an estimate may be seriously misleading due to several factors. It is well recognized that census data in Africa are often in error. Census data are further compromised by the fact that, in many areas, migration into urban areas is occurring at a rapid, often variable rate, and census figures only a year or two old may be seriously in error. Additionally, at any vaccination post, persons from a considerable geographic area may be attracted and the number of vaccinations tallied may be equal to the total number of persons living in the village where the vaccination post has been set up. However, an unknown number of vaccinees may have come from other areas.

A more accurate concurrent assessment of the effectiveness of vaccination coverage than can be provided through "tally data" is generally
required for an effective eradication program. This is described in later
sections.

2. Household and Village Registers

In some eradication programs, detailed household rosters have been developed and individual vaccination records have been kept for each household.

Assessments of vaccination coverage have been carried out by house-to-house visits, examination of the records and tabulation of the proportion vaccinated.

If records such as these are complete, and if well-defined sampling methods are used, the results can give reliable information. In practice, however, it has proved virtually impossible to keep records such as enumeration records or family registers up to date, complete, and/or accurate, especially in developing countries. (1) In programs where jet injectors are used, it is, of course, impractical to consider such detailed recording of information. At least 10 recorders for every vaccinator would be required.

A less elaborate version of the "total population register" has been employed in house-to-house vaccination programs. Vaccinators, in the course of
their work, have developed records as to the numbers of vaccinations performed

by age and sex and simultaneously a record of absentees or refusals. By such a system, a concurrent appraisal of population coverage should be available. The principal problem with this system lies in the fact that the assessment is not an independent function. Vaccinators have not generally been particularly conscientious with respect to recording absentees, especially when their work is judged, at least in part, on relative success in securing total coverage. A system such as this, of course, can be used only in the context of the house-to-house type of campaign and would not be applicable where jet injectors are employed. (2)

3. Challenge Vaccination

Challenge vaccinations have been proposed as a method for ascertaining the levels of immunity in a population. (3) This presumes, of course, that vaccination "take rates" can be equated to immunity level. Although the "challenge vaccination" approach would seem rather logical, difficulties are encountered in interpreting the findings. If a fully potent vaccine and reliable technique are used, 80 to 90% of revaccinees may demonstrate "major reactions" even though vaccinated recently. (4-5) Those not vaccinated for 10 to 20 years may be expected to show a somewhat different spectrum in the nature of the "takes" observed but observations are difficult to quantitate.

4. Serological Surveys

The logistics of bleeding significant numbers of persons and the cost and complexity of laboratory testing precludes sampling a meaningful number of persons. Serological surveys may be useful under highly selective circumstances but, at this time, represent a research tool rather than a practical operational tool.

5. Sample Surveys by Special Assessment Teams

a. Introduction and General Considerations

The use of sample surveys to determine vaccination coverage, by independent teams, has been found to be the method which provides maximum reliability consistent with reasonable simplicity.

The nature of the eradication program, limitations of personnel, the cultural context and the epidemiology of smallpox dictate to a considerable degree the particular methods which might be employed. Certain of the major considerations are:

- 1) Trained paramedical personnel are scarce. The methods used, therefore, must be as simple as possible, consistent with a minimum degree of functional reliability. "Sample" rather than "total survey" methods are required to decrease personnel demands. Careful supervision and training of personnel will be required.
- 2) The principle foci for endemic spread of the disease are believed to to be urban and market centers. Whatever assessment is carried out, therefore, needs to be focused principally on areas believed to be of major importance in the endemic transmission of the disease; urban areas and market centers. In these areas, particularly, repeat vaccinations programs may be required if coverage is inadequate.
- 3) The accuracy of interview data is generally felt to be questionable coverage is inadequate. The simplest means for determining the extent
 of vaccination coverage would be simply to ask residents as to whether
 they had or had not been vaccinated and, if so, when. Specific recognition of the term "vaccination", or any substitute term, is expected
 to be imprecise in most areas. It is probable, for example, that
 vaccination may be confused with other injections. If all vaccinated
 persons were to retain a vaccination card or certificate, specific
 identification of vaccinees would, of course, be possible. In practice,
 however, such cards have rarely been retained by enough individuals to
 permit their effective use. In large communal families in which the
 care of children is shared by many adults, the vaccination or injection
 status of some of these children may not be known or recalled. Finally,

al peoples. Thus, vaccination performed 6 months previously may not be differentiated in time from one performed many years before.

A feasible method for accurately identifying vaccinees for purposes of assessment is, thus, difficult to develop. The best method yet employed was utilized by Frederickson in Iran and Bolivia. (6-7)

Each vaccinee was asked to insert a finger in a small bottle of silver nitrate. This solution, painless and non-toxic, discolored the finger nail for a period of several weeks. At any time during this period it was possible to identify vaccinees. If an assessment survey is conducted anytime between one and two weeks following the vaccination program in an area, in which silver nitrate is employed, individuals who were vaccinated can be quickly identified; the proportion of vaccinations which represent successful primary takes can be readily assessed throughout a two week period due to the persistance of skin discoloration among primary vaccinees.

4) Parameters to be measured. Two distinct, but obviously related, results of vaccination team activities are to be assessed - percentage of vaccination coverage and percentage of vaccination "takes."

Percentage of coverage will be determined by a calculation based on a denominator consisting of all people living in the sampled house-holds and a numerator consisting of the people in the same households who were vaccinated in the current campaign (i.e. who have silver nitrate-stained fingers, if this is the marker used).

Percentage of vaccination "takes" will be determined on the basis

of a denominator consisting of those children in sampled households

who are observed to have the stained finger marker and a numerator

consisting of the children of this group who are observed to have had

a successful "take". This age group was selected because a large proportion of these children will have received their first exposure to smallpox vaccine during the current campaign, and there will be a minimum of revaccinations. However, this upper age limit is an arbitrary choice and it can be changed to suit local circumstances. If, for example, in some particular district there was an effective mass program 3 years previously, the percentage of "takes" can be calculated from observations on children up to 3 years old. The survey forms to be described in these guidelines should be appropriately modified.

While the routine assessment of revaccination "takes" will not be done there are a number of circumstances in which the assessment of revaccination "takes" will be most helpful. Of primary importance is the indication for assessing revaccination "takes" when there is any question about field vaccine efficacy. A vaccine which has sufficient potency to give a high "take" rate in primary vaccination may in fact be of insufficient potency to be effective for revaccination. Thus, successful "field titering" of vaccine efficacy will be possible only by assessment of revaccination "takes". In a program where laboratory resources for titering vaccines will be minimal, "field titering" by assessment of "takes" in revaccinees is the most efficient and effective way of monitoring vaccine potency.

The assessment of revaccination "takes" is a somewhat more specialized activity than the assessment of primary vaccination "takes". The influence of previous vaccination produces a variety of revaccination reactions and makes interpretation of results difficult in some instances. However, by using the WHO recommended procedures for assessing revaccination "takes" which include, a) a seven-day post-vaccinal reading and b) an examination of the site of vaccination for the presence of induration and evidence of vesicule or scar-formation, one can with reasonable assurance train local

personnel to make the differentiation between a "major reaction" and an "equivocal reaction" to revaccination. The "take rate" for revaccinees is then calculated using the total number of those vaccinated as denominator and the number of those with major reactions as the numerator. In previous experience using 1 to 10 dilution and jet injection intradermal vaccination, major reaction rates, even in persons previously vaccinated within one year, have approximated ninety percent. (5)

The indication for assessment of revaccination "take rates" may be simply stated. Anytime an assessment of "take rates" is undertaken as a serious monitor of the potency of vaccines, revaccinations must be assessed.

techniques of assessment to be outlined in the following, there will be many opportunities for informal, spot checks by American technicians and national authorities while on tour. Of particular interest might be the detection of entire villages omitted, from both vaccination and assessment, because they have been neither mapped nor censured.

b. Principles of Operation for Assessment Surveys

Based on the considerations set forth in the introduction, several guidelines may be provided with respect to the establishment of an assessment operation:

Assessment teams - To conserve trained manpower it would seem best to develop assessment teams (rather than to expect to train a larger number of individuals capable of working alone). With adequate training of the team leader and a lesser amount of training for other members, the team should be able to function as an independent unit. The output of the team should thus be of a quality consonant with the training and skill of the leader and capable of an output of work no less than might be expected if each individual endeavored to work alone. Further, transport problems are simplified since each team rather than each individual would require appropriate transport.

The number of persons to be included in each team, and the number of teams needed for each country program, will have to be dertermined by local circumstances and, ultimately, by local experience. Experience elsewhere indicates that each team member should be able to interview an average of 70 households per day in villages with less than 5000 population. On this basis, (and assuming that vaccination teams can cover 2,500 persons per day, on the average) in the rural area example to be given in the following, the assessment team would require approximately 41 assessordays and the vaccination teams would require 60 team-days. Similarly, the towns and cities from 5,000 to 100,000 population would require approximately 4 assessor-days each, regardless of size, while a city with 6,250 people would require 2 vaccination team-days; one of 12,500, 3-1/2 team-days; and one of 25,000, 8 team-days, based on an average of 3,500 vaccinations a day.

Therefore, as a very tentative work-plan for a rural area, it would appear likely that one assessment team consisting of a leader and one assistant could cover the work of 3 vaccination teams, if the latter work as a group in the same area. An assessment team of a leader and 2 assistants could cover the work of 4 to 5 vaccination teams. The same relationship could be developed for towns and cities depending upon their size.

If assessment team operations are projected for 20 work days per month (as has been done for vaccination teams), there will be sufficient lattitude to permit time for travel, leave, illness and other irregularities in scheduling.

2) Markers for Vaccinees - All individuals vaccinated should be "marked" for possible later identification in the assessment surveys. Use of silver nitrate solution appears to be the most workable "marker" yet devised although some form of indelible ink marking, for example, might be worth evaluating.

- Areas for survey Since the results from an assessment survey should be interpreted in terms of possibly needed changes in the approaches used by teams or may signal the need for further work in an area where coverage is inadequate, principle emphasis in assessment should be placed on urban areas and market centers. As a rule of thumb, surveys should be carried out in all urban areas of 5000 population or more and in market centers. The more sparsely populated rural areas must also be surveyed with sufficient intensity to provide general area information. This is necessary both to assess the adequacy of vaccination coverage, the methodology employed by vaccination teams in rural areas, and to provide data to be used in an evaluation of the percentage of coverage necessary to prevent transmission.
- 4) Time of survey The optimal time for survey is 7 to 14 days following vaccination in a given area.
- 5) Sampling method "Cluster Sampling"
 - a) Prior use of sampling techniques in Africa

The cluster sampling method, recommended for this program, has been employed successfully in Africa in a number of instances. For example, in Ethiopia it was used to establish baseline data for evaluating the effectiveness of the work done by the National Tuberculosis Center. (8) The survey covered all Ethiopians residing in Addis Ababa, utilizing the 1961 population census as the sampling frame and sampling clusters of 300 individuals each.

Cluster sampling has also been utilized in rural areas in Africa. In Ghana, a survey of the population and budgets of cocoa-producing families has been carried out using a single-stage cluster sample design. (9) In this survey a random sample of 90 districts was selected based on the enumeration areas of the 1948 population census.

Not only in Africa, but in other developing areas, the cluster sample has been used to great advantage. To increase the yield of interviewers, samples based not on individual dwellings but on clusters of dwellings were used in the Guanabara Demographic Pilot Survey in Rio de Janeiro, Brazil. (10) This was a joint project of the United Nations and the Government of Brazil to test a research method designed to estimate various demographic rates for a specific population. An approximate estimate showed that a random sample comprising 300 clusters of seven dwellings each, could be studied for the same cost as one of 600 individual dwellings selected at random.

Although a simplified assessment scheme based on cluster sampling will be described, more sophisticated sample designs have also been successfully utilized in Africa. A two-stage stratified sampling design was used in Gabon to collect income and expenditure patterns in monthly budgets of rural families and on qualities of supply and food stuff. The sampling frame was a complete list of villages in the two regions under study, arranged alphabetically by Canton and District. This information along with numbers of households in each village was available from the 1960-1961 census of Gabon. The sampling unit, which was a household, was defined as a group of persons of all ages sharing a common budget and sharing in common meals. In Nigeria, a nation-wide economic survey covering the entire rural area of Nigeria was conducted in 1963. (12) The survey covered 192 village units selected on the basis of a stratified multi-stage random sample.

Textbooks on sampling and papers dealing with cluster sampling have been utilized as background material for the preparation of these guidelines. (13-18) Serfling's Attribute Sampling Methods, an excellent field manual for immunization surveys, has been issued to all medical officers and operations officers. (19)

b) The Household as the Unit of Enumeration (20)

For the purposes of this program, the individual "household" would appear to be the preferred unit for the collection of data in a sample survey. The term "household", however, must be unambiguously defined to permit identification and subsequent enumeration of the members of each such group.

The internationally adopted definition (for census purposes) of private households recognizes two basic types of households, one-person households and multi-person households. A one-person household has been defined as a person who lives alone in (the whole or part of) a separate housing unit or who, as a lodger, occupies a separate room or rooms in a part of a housing unit but does not join with any of the other occupants of the housing unit to form part of a "multi-person household" as defined below. A multi-person household is a group of two or more persons who combine to occupy the whole or part of a housing unit and to provide themselves with food or other essentials for living. The group may pool their incomes and have a common budget to a greater or lesser extent. The group may be composed of related persons only or of unrelated persons or of a combination of both, as for example, a family with servants who live with them.

It is apparent that the general criteria for identifying members of a multi-person household are common housekeeping arrangements, a sharing of the principal meals in the sense that the household's food supply is obtained for common consumption or paid for out of a common budget, and in having common arrangements for supplying basic living needs.

However, in some certain instances, modification of the definition is required. In developing countries variations from the socalled "normal" family structure are common. These include: (1) a large proportion of informal (consensual) family relationships which are often of a shifting and temporary character; (2) the "extended family" structure in which all descendents of a common ancestor live together or in the same compound, resulting in a series of what in Western terms would be deemed separate households gravitating around the person of the family head; (3) the prevalence of polygamy, by virtue of which one man may be the head of several households which occupy separate housing units and (4) other types of communal living. In these cases the application of the recommended international definition of a household for identification and enumeration purposes requires extreme care.

The extended family, dispersed in a colony of housing units, and the several potentially separate family units which result from polygamous unions, present a problem since the definition of a private household nominally specifies occupancy of the same housing unit.

Assuming that the members share the principal meals and generally are regarded as one unit, the various "housing units" may simply be considered as separate sleeping quarters. If on the other hand, the various member groups also eat separately, they may be considered as separate households for enumeration purposes. If they are considered separate households, care must be taken to avoid over-counting of the husband who lives with different wives at different periods.

c) Sample Size

Without more detailed knowledge of household patterns and size of households, it is difficult to forecast the size of sample needed under varying situations. Some estimates are presented here for preliminary guidance. In general, they are conservative in that they propose a sample probably somewhat larger than may actually be required. If the sample sizes are employed, there is reasonably good

likelihood they will be large enough for our purposes. More definitive estimates will be worked out as information becomes available from field experience.

Five different sampling situations will be encountered:

- (1) Villages and towns under 5000 population
- (2) Towns and cities from 5000 to 100,000 population
- (3) Cities with over 100,000 population
- (4) Villages and towns with no readily definable separate housing units
- (5) Overall survey of a rural area.

(1) Villages and towns under 5000 population

Assuming an average household unit size of 5 (which experience may show to be an underestimate), a population in which 20% of the population is less than 5 years of age, and a desire to estimate the extent of vaccination coverage within ± 10% (with 95% certainty) for each of the four age groups (0-4, 5-14, 15-44 and 45+ years of age), calculations have been made to estimate the approximate sample size requisite for different sized villages and towns as shown in the table below. (See Annex I for a detailed description of the methodology.)

Estimated Population	estimated No. of Housing Units(N)*	Sample Size(n) No. of Housing Units	Sampling Ratio**
500	100	67	1
1,000	200	100	1/2
1,500	300	120	1/2
2,000	400	133	1/3
2,500	500	143	1/3
3,000	600	150	1/4
3,500	700	155	1/4
4,000	800	150	1/5
4,500	900	164	1/5
5,000	1000	167	1/6

^{* 5} persons per household

^{**} Rounded off to the next highest fraction

We can then sub-group towns and villages with less than 5000 persons in five sampling categories as shown below:

Size of Vi	llage or Town		Possible
Estimated Population	Estimated No. of Housing Units	Sample	Sample Size (No. of Housing Units)
5 - 999	1 - 200	All houses	1 - 200
1000 - 1999	200 - 400	Every second house	100 - 200
2000 - 2999	400 - 600	Every third house	133 - 200
3000 - 3999	600 - 800	Every fourth house	150 - 200
4000 - 4999	800 - 1000	Every fifth house	160 - 200

In principle, the method to be employed in selecting the housing units for survey is the following. If, for example, one fifth of the housing units are to be sampled, the interviewer may be given a small table of the numbers 1, 2, 3, 4 and 5 in random sequence to be used as a guide in selecting the housing units. The interviewer is instructed to count the dwelling unit at either end of the village or town as housing unit #1 and take the first interview at the housing unit corresponding to the first unused number in the random table. Thereafter, every 5th housing unit in the village or town is interviewed in a systematic manner. An example of a small random number table for this purpose is shown below:

5 5 5 4 2 2

Therefore, if an interviewer started down the first column of random numbers, he would first interview housing unit #4 in the first village and continue on with housing unit nos. 9, 14, 19, 24, 29

In the second village, the interview would begin with housing unit #1

and then take every fifth house as above, or housing unit nos. 6, 11,

In practice, it will often be found nearly impossible to count housing units in the organized manner that is possible with the orderly arrangement of houses along an Atlanta street. In the circumstances of a completely unplanned community, compromise will be necessary, but must not sacrifice the principle of randomness. By simple inspection, clusters of five (or any other number) houses can be identified, and, in a consistent manner, one unit selected for inclusion in the sample.

(2) Towns and cities from 5,000 to 100,000 population

As shown in Annex I, a minimum sample of 200 housing units is necessary for towns and cities with 5,000 to 100,000 persons. In this situation, the block or some area similar to a block will be the primary sampling unit rather than the housing unit.

As discussed in Annex II (Variances and Significance Tests), a minimum of 30 primary sampling units (p.s.u.) is necessary. A conservative estimate of 28 housing units per block would require every fourth housing unit to be interviewed in order to obtain an average of 7 interviews on each of 30 blocks. With 30 blocks serving as the p.s.u., an average of 7 interviews on each block should yield 200 housing units and 200 children under 5 years of age. (As before, we are working under the assumption that 20% of the population is under 5 years of age and there are five persons per housing unit so that the number of housing units and number of children under 5 is the same.)

If definable blocks are not available, areas of at least 28 housing units each should be drawn up.

To select the 30 blocks, use the best available street map or city planning map on which the blocks may serve as a sampling frame.

All blocks (or block areas), which are known not to contain any housing

units are marked on the map and excluded. These may be blocks containing exclusively such structures as office buildings and stores, schools, churches, hospitals, parks, industrial establishments, etc.

With these blocks removed from consideration, a rough count is made of the number of blocks remaining and they are numbered from 1 to N.

At the same time, an estimate of the number of housing units on each block should be made. Thirty of these are then randomly selected with probabilities proportional to their size (number of housing units on each block) utilizing a table of random numbers which is included in Annex III. See Section (5), Overall Survey of a Rural Area, p. 21-25, for a detailed example of random selection with probabilities proportional to estimated size. Within each block selected, every 4th housing unit, with a random start, will be surveyed yielding an average of 7 housing units per block and an average of 210 housing units per town or city.

(3) Cities over 100,000 population

cities this size may present special problems in size, socioeconomic differences, and the possibility that some other epidemiological variables may be useful to include in a survey of a larger
city. Only Ghana and Nigeria have more than one city over 100,000
population. Some of the countries in the program have no cities of
this size.

Therefore, due to the unique problems presented by cities of this size, it is recommended that these cities be surveyed only with the consultation, assistance and guidance of the RPO statistician. The possibility of using Peace Corps volunteers or trained Nationals from outside the program as interviewers in the larger cities should be considered.

(4) Villages and towns with no readily separable housing units

In areas where large compounds prevail, with a large number of persons gravitating about the person of the family head, separate housing units may be difficult to define. If the number of compounds can be determined along with an estimate of the total population, the requisite number of compounds to be sampled can be calculated. For example, if there is a village with 40 compounds and an estimated population of 2,000, the average compound population would be 50. In Africa, approximately 20 percent of the population is under 5 years of age so that we can expect, on the average, 10 children in this age group in each compound. As discussed in Annex I, a sample of 200 children under 5 years of age will yield the number of persons needed in the older age groups. Thus, to include 200 children under age 5 in the survey, 20 of the 40 compounds would need to be sampled, etc.

Under some circumstances, it may prove difficult or impossible to undertake sampling in areas of this complexity. In large parts of the savannah-sahara area, villages sometimes assume the form of continuous walls with occasional doors or windows but no distinctive household unit separation is visibly evident. Only a door-to-door window-to-window type survey could possibly define the tangled skein of household units. In such a situation, there are no guidelines. If there are several segments or sections of such a village visibly separate, a total survey of all residents in randomly selected segments might be undertaken with the hope that the rather gross segments selected were reasonably representative of the experience of the village as a whole. Again, an effort should be made to sample a population large enough to include about 200 children under 5 years of age.

(5) Overall survey of a rural area

An overall survey of a rural area is reasonably complex and will

require careful planning and scheduling if it is to be carried out.

An illustration of how this might be done is outlined below for hypothetical Medical District X with a population of 193,500 persons grouped in villages and towns as follows:

Population	No. of Villages	Total Population
<5000	216	151,000
5000+	2	42,500

The two towns of greater than 5000 population also represent the only market centers in this area. Since all towns of greater than 5000 are to be sampled as are all market centers, an assessment survey of these two towns, as outlined on p.19 and 20, plus a sample of the rural village area is indicated.

To obtain a reliable estimate of coverage in the rural area, a random sample of 30 of the 216 villages or towns with less than 5,000 population has to be selected for assessment. From a list of the 216 villages and their estimated population, 30 should be selected at random with probability proportional to population.

To select 30 villages with probability proportional to population, we would set up the following table:

Village No.	Estimated Population	Population (Hundreds)	Cumulative Population (Hundreds)
1	282	3	3
1 2	716	7	10
3	384	4	14
4	258	3	17
5	461	5	22
6	158	2	24
7	4292	43	67
8 9	140	1	68
	755	8	76
10	225	2	78
11	417	4	82
12	514	5	87
13	967	10	97
14	883	9	106
15	392	4	110
16	220	2	112
17	489	5	117
18	504	5	122
19	581	6	128
20	1204	12	140
• £8	· 01	33 - • - 58	• 614
• 69	•	• 69	• 250
216	131	i	1510

We now need to select 30 numbers between 0001 and 1510 from a table of random numbers (Annex III). Let us assume that 6 of the 30 random numbers selected were 68, 80, 108, 112, 121 and 138. We note that 68 falls in village no. 8, 80 falls in village no. 11, etc.

(any number between 79 and 82 would fall in village 11). In this manner 30 villages would be randomly selected and we will assume that the following 30 villages were selected.

Village No.	Estimated Population	Estimated No. of Housing Units (5/h.u.)	Sampling Ratio	Estimated No. Household Units in Sample	Approximate Assessor Days Required*
39	827	165	1:1	165	2.5
185	217	43	1:1	43	0.5
69	483	96	1:1	96	1.5
21	52	10	1:1	10	0.5
30	164	33	1:1	33	0.5
84	251	50	1:1	50	1.0
31	2924	585	1:3	195	3.0
37	557	111	1:1	111	1.5
18	504	101	1:1	101	1.5
25	415	83	1:1	83	1.0
45	769	154	1:1	154	2.0
71	3887	777	1:4	194	3.0
131	984	197	1:1	197	3.0
107	565	113	1:1	113	1.5
8	140	28	1:1	28	0.5
16	220	44	1:1	44	0.5
	392	78	1:1	78	1.0
15				77	1.0
61	384	77	1:1	111	1.5
176	555	111	1:1	121	1.5
20	1204	241	1:2	83	
11	417	83	1:1	69	1.0
112	345	69	1:1	32	0.5
46	158	32	1:1		
68	504	101	1:1	101	1.5
82	4480	896	1:5	179	2.5
26	1099	210	1:2	105	1.5
104	140	28	1:1	28	0.5
28	132	26	1:1	26	0.5
191	79	16	1:1	16	0.5
70	802	160	1:1	160	2.5
Total	23650				41.0

^{*} Assuming an assessor can reach 70 houshold units each day and assuming the need for at least one-half day in each village (rounded off to nearest half day).

Approximately 41 assessor days would be needed. Using this scheme, estimates for vaccination coverage and take rates can be presented for each individual village using the housing unit as the sampling unit and estimates for the entire rural area can also be made using the village as the primary sampling unit.

In some areas, villages may have an average population of 100 to 200, rather than the 700 in the example given on the previous page.

Where this is true, the assessment method is the same, but the number of assessor-days required will be greater because of the greater amount of travel time necessary. However, vaccination teams will have the same difficulty, and vaccination-assessment activities should remain in phase.

As stated previously, assessment surveys should be done one to two weeks following vaccination. The schedule of vaccination centers should be known in advance. When any of the 30 villages selected for assessment are scheduled for vaccination or are included in an area to be covered by a scheduled vaccination center, that village can then be scheduled for assessment 7 to 14 days later. However, the vaccination teams should not know the 30 villages selected for assessment.

It should be noted that most villages are not compact units, but consist of a principle village surrounded by satellite "hamlets", or only of a cluster of more-or-less district "hamlets". The relation-ship of the hamlets to each other, and to the central village, will be recognized by local tradition. For purposes of assessment, the clusters should be treated as one unit; since this follows local tradition and often hamlet names reflect this, this should cause no confusion and should make selecting the sample much simpler than treating each hamlet as a separate village.

d) Assessment Forms

Sample survey forms for assessment of vaccination coverage are included (figures 4 and 5). Provision is also made for recording the number of "takes" for vaccinated children under 5 years of age on the same form.

The first survey form (figure 4) is for towns and villges with less

than 5,000 population. Once the villages in any given geographic area are selected for assessment, the information at the upper portion of the form can be filled in listing the village or town, medical district (or circumscription, etc.), estimated population and estimated number of households. A survey in a given village should be scheduled about 7 to 14 days following vaccination. Based on the estimated population, the sampling ratio can be determined (as previously described). For example, if the village to be surveyed had an estimated population of 1,500 persons, the assessor should sample every second house in the village. If the population estimate is fairly accurate (and assuming about 5 persons per household), around 150 households would be sampled in this village. In this situation, either the first or second house would be selected randomly. Assuming that 2 was the number selected the remaining blanks in the upper portion of the form would be filled in to read: Begin survey with house no. 2 and visit every second house. After similar forms have been prepared for each town or village in the current block of work, they are given to assessors assigned to each, together with the date(s) they are scheduled to assess each village. For the village with an estimated 1,500 persons, approximately two days would be required to complete a survey and two dates would have been filled in the appropriate space on the survey

When the assessor visits a household he should first determine how many children there are under 5 years of age in the household. He should mark down the number of these children in the first column under "0-4 years of age". He should then determine how many were vaccinated (the number of children with silver nitrate on their finger) and enter the number with silver nitrate stained fingers in the "number vaccinated" column. For children under 5 years of age, the assessor should then look at (inspect) the vaccination site of all those with silver nitrate staining and record

the number with a "take". Therefore, for those under 5 years of age, the assessor would be listing the number in the house, the number vaccinated, the number of vaccinees inspected, and of those inspected, the number with a "take". He would then determine how many persons there are from 5 to 14 years of age, 15 to 44 years of age and 45+ years of age in the household. For these older persons the assessor would only have to determine the number in the household and the number vaccinated (those with silver nitrate staining).

Actual experience in the field will almost certainly reveal that not all members of the household are present at the time the assessor visits. Since it will not be possible to revisit households, nor to search for missing members in order to examine them, some dependence upon history will be necessary. It is reasonable to accept the statement of a responsible member of the household as to the number of persons living therein (first column in each age group) and the number with stained fingers as this is likely to have occasioned some family discussion (second column, "number vaccinated"). It is not permissible, however, to accept historical information about vaccination "takes". For children 0 through 4 years of age, therefore, it will be necessary to also record the number with stained fingers actually observed and inspected by the assessor, and, of them, the number observed with "takes".

Recall that the age group selected for assessment of percentage of vaccination "take" was arbitrary (Section B.5.a.4), and that it may be changed to suit local circumstances. If this is done, the form may be modified as appropriate, but the age group "0-4 years" for assessment of coverage must not be changed.

Each line on the form represents a household. The assessor is able to list the information for 30 households on the first page of the survey form for any given village. He could then utilize continuation sheets, each containing 34 lines. Five of the continuation sheets plus the first

page of the survey form will have exactly 200 lines.

In using the survey forms for towns and cities with greater than 5,000 population, the assessor would be required to visit 30 randomly selected blocks and obtain the same information as discussed for the previous form. On each block, the assessor would visit every fourth household, resulting in an average of seven households. On the form (figure 5), block number is listed in the left hand column. Each line represents one block and there is room for 12 blocks on each form if there are no more than 17 persons in any age group on a single block. If there are more than 17, an additional line would have to be used with number 1 on the second line representing the 18th person on the block. The assessor should encircle the number "1" and then each successive number in each column as he encounters and examines the people in the entire block; he need not separate households in any given block. For example, on block X, the assessor interviewed every fourth house beginning with the 2nd house on the block. There were 31 houses on the block so he interviewed house nos. 2, 6, 10, 14, 18, 22, 26 and 30. In these 8 households on block X, he found 13 children under 5 years old, of which 11 were vaccinated. Of the 11 who were vaccinated, the assessor inspected 10 who were available and 9 had a "take". The appropriate section of the survey form is shown below for block X:

Block	No. in	No.	No.	No. with
No.	House	Vacc.	Inspected	
x	9000 0000	0000 6000	0000 0000 0011	\$234 \$678 \$10 11
	C G 14	12 13 14	12 13 14	12 13 14
	15 16 17	15 16 17	15 16 17	15 16 17

The comment made on the use of figure 4, concerning the acceptability

of history for determining percentage of vaccination coverage but the

necessity for direct observation for determining percentage of vaccination

"take", is equally applicable to figure 5.

6. Vaccination Scar Survey

In developing countries, it is difficult to assess the vaccination status of the population in a defined geographic area, in other than assessment surveys immediately following a vaccination program. As previously noted, there may be considerable confusion regarding vaccination as opposed to any other injections, the sense of time intervals is often poor, etc. Nevertheless, it may be of interest to have some information about the extent and effectiveness of vaccination activities in the past. Examination of vaccination scars in young children provides the best and least confusing data with respect to effective vaccination activity in an area in recent years. For example, if almost no children under 3 years of age have typical scars, and of those 3 to 4 years old, 50 to 60 percent have scars, it is reasonable to conclude that there was a vaccination program in this population group about three years ago but that the coverage and/or percentage of "take" was not very good.

A survey for vaccination scars is probably the only practicable method available for assessing a maintenance infant vaccination program which is based upon routine immunization at health centers after the completion of the mass attack phase. For such a purpose, only children born since the mass program (the date of which will be known precisely) need be examined.

7. Terminal Assessment

By "terminal assessment" we mean the determination of the vaccination status of an entire province, Department, nation, or large tribal group after the completion of the vaccination program in that geographic area. Such an assessment serves two separate purposes which cannot be separated. First, it constitutes a summary of all the previous "concurrent" assessments which were conducted immediately following the vaccination program locally, and which had as their purpose the detection of local shortfalls in order to permit continued or repeat work or changes in program tactics. Together with a review of the

results of concurrent assessments, and all other pertinent data, the terminal assessment provides the basis for "certifying" the satisfactory completion of that phase of the program. Second, and perhaps more important, terminal assessment provides a summary of successful vaccination in a large area containing mobile populations which may have moved into and out of localities scheduled for vaccination at very different times (even from one nation to another with perhaps very different programs). It might be possible to demonstrate that every local program had reached 80 to 90 percent of the population with potent vaccine, and that 50 percent of the people had been missed because they had moved from localities which had not yet been reached into localities through which the teams had already passed. Only large-scale, terminal assessment could detect such a phenomenon.

Since vaccination will have been performed long before terminal assessment, and since we have no permanent marker system, only vaccination scars can serve to indicate that vaccination was successfully performed. Since only children who were living at the time of the mass campaign being assessed, and who had been born subsequent to any previous campaign, were the certain targets of primary vaccination during the most recent mass campaign, most interest devolves upon them. However, all persons, regardless of age should be included because we are interested in assurring that everyone has had vaccination at some time. Therefore, the basis for terminal assessment is the determination of the percentage of persons who have vaccination scars - in all age groups, but with principal emphasis on the young children defined above.

The sampling method used is essentially that described in "Overall survey of a rural area," above. The selection of the geographic areas epidemiologically appropriate for terminal assessment, and the construction of appropriate sampling frames and techniques, are complicated problems that must be solved individually. Such assessments which might have to be coordinated internationally must therefore be planned in consultation with the Director and

Statistician of the RPO. The Chief and Statistician in Atlanta may also Have to be consulted since some terminal assessments may be "independent" in nature and may require association with WHO or other organizations.

cision must be made about the system of the population unceinated in the application program, we want to aspess the coverage of the population unceinated in the age wroups 0-4, 5-14, 15-44 and 45 and over. In addition, we want to assess "take nates" or successful veccination to the children under 150e years of age.

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Estimation of Sample Size

In the planning of a survey method, a stage is always reached at which a decision must be made about the size of the sample. In the smallpox eradication program, we want to assess the coverage of the population vaccinated in the age groups 0-4, 5-14, 15-44 and 45 and over. In addition, we want to assess "take rates" or successful vaccination in the children under five years of age.

A. For Vaccination Coverage

To assess the vaccination coverage by age group in a city, town, or rural area, we would like our estimate of vaccination coverage to be correct, except for a 1 in 20 chance, within \pm 10%. The use of the 0-4 age group can serve as an index group for calculation of sample size as they will insure an adequate sample in the older age groups since this group will have the smallest numbers of the four age groups (0-4, 5-14, 5-44, 45 and over). We can expect the coverage of the population to be anywhere from some percentage less than 50% to complete coverage of 100%. Since the product of pq increases as p moves towards 1/2, or 50%, a conservative estimate of n is obtained by choosing for p the value nearest to 1/2 in the range in which p is thought likely to lie. Therefore, we will utilize p = .50 in the calculation of sample size: $n = \frac{t^2}{d^2}$ pq where p = 0.50

d = 0.10, the margin of error
t = 1.96, the value for d \(\times \) 10%
for a 1 in 20 chance

$$n = \frac{3.84 (0.50) (0.50)}{0.0100} = \frac{0.9600}{0.0100} = 96.00$$

In a survey of families the sample is formed consisting of clusters of one, two or more children. If, in each family, the chance that a child is immunized were independent of the chances that his siblings are immunized, a sample of families would be equivalent to a simple random sample of children and the binomial variance formula V(p) = p(1-p) or pq could be used.

However, this is not the case as shown in basic texts on sampling and as described in Chapter 11 of Attribute Sampling Methods. It is quite clear that

there is a strong association with respect to vaccination status of children within families or within villages (if villages were the primary sampling unit). Therefore, the binomial variance formula should not be used to calculate the precision of estimates of immunization levels (or other correlated attributes) when families are the sampling units or another primary sampling unit is used as the basic cluster. To compensate for increase in variation resulting from within family correlation, or correlation between families within primary sampling units, the sample size calculated previously has to be multiplied by a clustering coefficient. Serfling has estimated this cluster coefficient for smallpox immunization in children under 5 years of age to be 1.85 (See Chapter 11 - Attribute Sampling Methods).

We then multiply our sample size of 96 by the clustering coefficient of 1.85 and obtain 177.6 or 178 as the necessary sample size for children 0 to 4 years of age. In addition, we may estimate a vacancy and/or not-at-home rate of about 12% in the households falling in the sample so that we can add another 22 children to the sample to make our sample size an even 200.

In developing areas, at least 20 percent of the population may be under 5 years of age. If an average household size is 5 persons per household so that we are expecting 1 child under 5 in every household, we can use the number of children under 5 and the number of households as a synonomous figure. To obtain 200 children under 5, we would then need to sample 200 households which should include 1000 persons of all ages.

However, as discussed in Cochran and Serfling (13,19), the sample can be reduced by means of a finite population correction (fpc) if the sample size (n) is large relative to N, say 10% or greater. In our situation, we have selected n to be 200 children under 5 years of age which will be 10% or greater for N equal to or less than 2000. We have made the further assumptions that, on the average, there will be one child under 5 years of age in each housing unit and there will be an average household size of 5 persons. With these assumptions, 200 children under 5 years of age will then become synonomous with 200 housing units. Thus, 200 housing units (1000 persons) will be at least 10% of any village or town up to

To be conservative, we will introduce the finite population correction only when $\frac{n}{N} > 20\%$. Thus, for villages and towns with less than 5,000 population, we can apply the finite population correction, f.p.c. = $\frac{n}{1 + n/N}$ to reduce the sample size necessary but retain the precision desired. We can illustrate this reduction in sample size in the following table.

Estimated Population	Estimated No. of Housing Units(N)*	Sample Size (n)	Corrected Sample Size**	n/N	Sampling Ratio***
500	100	200	67	.67	al quiet
1,000	200	200	100	.50	1/2
1,500	300	200	. 120	.40	1/2
2,000	400	200	133	.33	1/3
2,500	500	200	143	.29	1/3
3,000	600	200	150	.25	1/4
3,500	700	200	155	.22	1/4
4,000	800	200	160	.20	1/5
4,500	900	200	164	.18	1/5
5,000	1000	200	167	.17	1/6

^{* 5} persons per household

** fpc =
$$\frac{n}{1 + n}$$

*** Rounded off to the next highest fraction.

B. For Vaccination "Take Rates"

To assess the potency of vaccine, it may be desirable to determine the proportion of successful vaccinations in children under five years of age. If comparatively few of those under 5 years of age had been vaccinated previously, a take rate of 90 percent would be reasonable evidence that potent vaccine had been used. Although normally, one would anticipate a take rate in excess of 95% for primary vaccinees, it is assumed that some of these children will represent revaccinees. Some allowance must be made for sampling error. In general, we will tolerate the estimated take rate to be correct within plus or minus 6 percent. This would mean that, if the sample showed 84 percent to have a "take", the "true" percentage for the whole population under 5 should be between 78 percent and 90 percent. Having accepted 0.06 (d) to be an acceptable margin of error for the estimated proportion, and recognizing that there is a small risk (x) = 0.05 which

we are willing to incur that the actual error is larger than d, calculation can be made regarding the requisite sample size in different population. A sample result of 84 percent "takes" would be accepted as the minimum "acceptable" take rate for smallpox vaccination as the margin of error would include 90 percent except for a 1 in 20 chance.

In technical terms, p is to lie in the range $p \pm 6\%$ except for a 1 in 20 chance. Since p is assumed normally distributed about P, it will lie in the range $p \pm 6\%$ (p + 25p) apart from a 1 in 20 chance.

To calculate the sample size, we again solve $n = \frac{t^2 pq}{d^2}$

where d = margin of error (6%) and t = value for d ₹ 6% except for a 1 in 20 chance

If n/N is not negligible (greater than 10%), as discussed on page 33-34, we would utilize the finite population correction to obtain a better approximation of n as follows:

$$fpc = \frac{n}{1 + (n/N)}$$

However, in our problem of assessing take rates, we will assume that n/N is negligible and the take rate should be at least 84 percent. We then have:

or

$$n = \frac{3.84(0.84) (0.16)}{0.0036} = \frac{0.5161}{0.0036} = 143.4$$

Thus, in a given area, 143 children under 5 years of age should be adequate to measure vaccine efficacy in terms of the "take rate" of children vaccinated. However, in a given village, not all children will have been vaccinated and a greater number of children will have to be sampled to include 143 who have been vaccinated. With the assumption that only 70 percent of the preschool age group were vaccinated, approximately 200 children would need to be sampled to find 143 who had been vaccinated. Since we would like to assess "take rates" in those under 5 years of age at the same time vaccination coverage is

assessed in the entire population, we can use the previously computed sample size of 200 for both purposes.

Since the reaction to smallpox vaccination in each child is an independent event, the binomial variance formula (v)p = pq may be used to show the precision of the estimated "take rate". The "take rate" would represent the number of children with "takes" divided by the number vaccinated.

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ANNEX II

Variances and Significance Tests

To evaluate the precision of the findings the standard deviation (square root of the variance) must be calculated for the estimate of coverage, the take rates and/or any other epidemiological variable that is measured.

For estimates of coverage, variance formula (9.1) as described in Chapter 9 of Attribute Sampling Methods should be used when the village or block is the primary sampling unit. When the family or housing unit is the basic sampling unit the "ratio" variance formula (11.6) as described in Chapter 11 of Attribute Sampling Methods should be used. Formula (9.1) is analogous to formula (11.6) but is adopted for use of the primary sampling unit, rather than the individual family, as the basic cluster. The family data is pooled within each primary sampling unit for formula (9.1). For take rate estimates, binomial variance formula (11.4) may be used.

Averages and their variances and comparison of the proportion immunized in two areas is also discussed in Chapter 9 of Attribute Sampling Methods. The derivation and discussion of sampling formulas is presented in Chapter 11 of Attribute Sampling Methods.

ANNEX III

Table of Random Numbers*

Random number tables may be used for making random choices in the same manner as tossing a coin to decide between two alternatives or casting a single die to select randomly one of six possibilities. The advantage of the random number tables lies in the fact that adjustments can quickly be made to select one or more out of any number of possibilities. The short table included here consists of columns of two-digit numbers, ranging from 00 through 99.

As a simple example suppose that one wished to use the random number table to select one of two alternatives. One would classify one-half of the numbers from 00 to 99 as representing one alternative. These could be the numbers 00-49. The remaining fifty numbers (50-99) would then be classified as representing the second alternative. With eyes closed, make a "random stab" at a page of the table so that one or more of the numbers is obscured. Lift the finger, and if the first observed number is from 00-49, the result indicates choice of the first alternative; if it is a number from 50-99, the second alternative is indicated.

As a second example assume that one wished to choose at random a number from one through seventeen. Proceed as above in selecting a number. If the number found is in the range 1-17, "05" for example, take 5 as the chosen number. If the first number observed falls outside the range 1-17 continue down the column until a number falling within the range 1-17 is obtained.

The "random stab" procedure will be satisfactory if only a few numbers are to be chosen, in which case one can move from one page of the tables to another. When a large number of selections are to be made this procedure is not desirable since one may tend to repeat the same initial choice. In this case it is better to select one initial starting point in the table by a random procedure and then proceed systematically down the column and on to the next throughout the table. To select a random starting point choose one of the five pages at random by letting page 1 correspond to the range of two place digits 00-19, page 2 to the range 20-39, etc. Use the "random stab" method to select a page, then select a number from 1 through 30 to determine a row and a number from 1 through 20 to determine a column. Take the number at the intersection of row and column on the previously chosen page as a starting point.

^{*}Prepared by Statistics Section, Epidemiology Branch, CDC, BSS, PHS, DHEW, January 15, 1959.

	No.																			
	1,2	30	23	87	49	19	33	18	41	96	c 6	26	87	97	CO	63	30	37	40	25
	24	29	42	59	75	56	23	86	92	65	58	36	01	17	65	53	51	03	80	59
* COMMON	38	84	27	64	95	05	05	49	73	86	94	44	54	27	28	82	96	76	04	52
	79	14	98	28	26	89	57	06	50	58	74	66	16	15	62	19	70	25	52	48
	18	73	65	06	62	47	68	83	61	98	92	20	63	29	85	35	70	67	19	c 9
•	62	53	12	65	30	27	33	71	39	57	38	57	52	92	64	78	71	18	61	99
87-3	90	21	03	75	26	41	57	49	10	08	61	38	64	51	04	06	03	52	79	94
y Pân S	81	72	57	66	45	92	71	89	31	53	45	41	17	52	24	07	25	83	16	21
1190-1	57	48	47	27	21	83	57	80	06	13	27	43	52	10	12	53	44	39	63	32
	75	36	68	03	56	16	87	37	77	72	34	56	65	99	45	62	25	54	24	09
	41	68	73	93	85	69	12	79	09	02	53	95	80	75	00	94	19	68	56	06
	87	17	74	47	91	92	03	62	94	52	91	31	97	29	14	19	21	45	99	30
	70	36	84	17	41	36	36	35	40	22	19	68	69	18	56	74	94	56	86	76
	10	85	11	47	70	60	17	80	52	62	31	45	81	04	37	69	14	25	93	23
	81	55	99	81	67	91	81	95	55	23	96	88	06	35	95	73	60	06	40	35
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	_ 75	3	09	26	92	50	99	25	36	09	81	42	04	50	47	76	13	15	30	32
	60	71	28	71	78	45	47	75	98	26	96	46	45	61	58	67	25	50	90	09
	41	01	70	57	56	04	02	66	65	46	33	67	73	09	42	33	05	71	92	02
	56	41	77	07	17	78	10	85	27	55	51	21	74	66	42	14	49	25	23	13
	58	27	06	67	31	90	65	58	13	53	32	21	85	76	77	22	45	13	81	77
	19	24	74	72	91	24	37	30	82	05	41	37	09	87	93	79	14	30	45	82
	66	27	05	35	26	55	49	80	89	18	58	30	21	91	10	46	76	56	81	71
***************************************	96	16	52	86	84	54	22	70	37	09	81	66	32	18	49	C4	52	45	87	55
24	36	18	19	64	98	51	76	31	12	30	86	30	95	31	93	66	80	28	90	86
	59	73	20	25	60	60	32	29	67	17	36	54	33	90	07	27	41	95	24	78
	07	78	22	51	91	91	73	20	00	60	73	07	38	33	49	49	96	57	11	05
	31	20	45	95	40	06	76	37	95	23	14	28	72	36	80	56	35	05	76	51
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ANNEX IV

UNITED NATIONS STATISTICAL EXPERTS ON FIELD ASSIGNMENTS IN WEST AFRICA (UN Statistical Office)

Expert	Nationality	Assignment	Country	Assignment Expires
		UNITED NATION	<u>s</u>	
W. L. Booker	(UK)	Regional Statistical Advise on Secondment to ECA	er,ADDIS ABABAl	18 June 1967
A. Couday	(SYR ARAB REP)	Statistical organization	UPPER VOLTA	25 Oct. 1966
Miss K. Jupp	(ÁUSTRALIA)	Regional Statistical Adviser, Africa, demograph statistics	ADDIS ABABAl	21 July 1969
V. O. Kannisto	(FINLAND)	Demographic statistics	NIGERIA (extens	30 June 1966 sion in process)
M. Kovacka	(CZECHOSLO- VAKIA)	Industrial statistics	GHANA	31 Oct. 1966
K. W. Masters	(USA)	Economic statistics	NIGERIA	2 Sept. 1966
V. N. Murti	(INDIA)	Economic statistics	NIGERIA (Eastern Region)	23 Feb. 1966 (ext. in process)
N. Naoumov	(BULGARIA)	Statistical organization	MALI	29 Sept. 1966
Mrs. N.Thi Nguyen	(REP OF VIET- NAM)	National accounts	rogo (one-year extension	17 Dec. 1965 on in process)
K. Miltenyi	(HUNGARY)	Vital statistics	GHANA	26 June 1967
C.S. O'd Scott	(UK)	Regional statistical Adviser, Africa, Sampling	ACCRA ¹ (from 15 Jul 63)	31 Dec. 1966
K.N.C. Pillai	(INDLA)	National accounts	SIERRA LEONE	6 Nov. 1966
B. Ramamurti	(INDIA)	Chief statistician (OPEX)	NIGERIA	30 Sept. 1966
A. Serre	(FRANCE)	Director of Studies Yaounde Training Centre	CAMEROON	31 Oct. 1966

¹ Duty Station

				Assignment
Expert	Nationality	Assignment	Country	Expires
M. Shrivastava	(INDIA)	Economic statistics (training)	NIGERIA (extens	11 July 1966 ion in process)
R. S. Asthana*	(INDIA)	Agricultural statistics	NIGERIA (M.W.)	31 Dec. 1966
A. Diaz*	(SPAIN)	Agricultural statistics	GABON	31 Dec. 1966
J. Faber*	(NETHER- LANDS)	Associate Expert to work with Mr. Kallmeyer	GHANA	31 Dec. 1966
V. F. Golovchenko*	(USSR)	Agricultural statistics	MALI	31 Dec. 1966
N. K. Iren*	(TURKEY)	Agricultural statistics	UPPER VOLTA TOGO	31 Dec. 1966
H. Kallmeyer*	(GERMANY)	Agricultural census	GHANA	31 Dec. 1966
H. C. Gupta**	(INDIA)	Educational statistics	LIBERIA	Oct. 1966
P. Maes**	(FRANCE)	Educational statistics	CENTRAL AFRICAN	Sept. 1966
L. A. Roy***	(FRANCE)	Tuberculosis survey team	WEST AFRICA	Oct. 1967
P. Sadek***	(UAR)	Tuberculosis advisory team	NIGERIA	March 1967
A. Vessereau***	(FRANCE)	Vital and health statistics	SENEGAL	July 1967
Charles Benrud****	(USA)	Rural economic survey	NIGERIA	Unk.
James M. Daley****	(USA)	Rural Economic Survey	NIGERIA	Unk.
Albert W. Graybill*	***(USA)	Agriculture Statistics Adviser	SIERRA LEONE	Jan. 1967
Abner Hurwitz****	(USA)	Principal statistical Adviser	SIERRA LEONE	March 1968

^{*} Food and Agriculture Organization

** United Nations Educational, Scientific and Cultural Organization

*** World Health Organization

*** Agency for International Development

Vaccination Tally Sheet

Age	Age	
Group	MALES Group	FEMALES
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	1 2 3 4 3 0 7 0 7 10 11 12 13 14 13 10 17 10 17 10 17	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 60 LOG PAGE
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	1 2 3 7 3 0 7 0 7 10 11 12 13 17 13 13 17 17 17 17 17	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 60 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 80 MED. DISTRICT
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		2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 20 VACCINATION
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Vaccination Summary Sheet

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Monthly Vaccination Report for RPO

Vaccinations Performed by 4-Week Period

				Smallpox Vac	cination
	Province or County Unit	Estimated Population (Total)	Measles Vaccinations Performed	Vaccinations Performed	Estimated Percent Coverage
1					
2					
3					
4					
5					
6					
7					
8					

SMALLPOX VACCINATIONS PERFORMED

	K1	1-4	5-14	15-44	45+	TOTAL
Males						
Females						
TOTAL						

SMALLPOX ERADICATION PROGRAM

SURVEY FORM FOR

Towns and Villages with Less than 5,000 Population

Villa	ge or To	wn		O MATERIA	_	Estimat	ed Populat	ion	1.00	117
Medic	al Distr	ict _				Estimat	ed No. of 1	Households		_
Date	Village	Vaccina	ted	Tell III	AT ASP 1	Date(s)	of Survey			
			use No			,	house.			
-			s of age		5-14 years	No. No. in N	rs of age	45+ year	s of ag	
No.	No. in House	No. Vace.	No. Inspected	No. with "Take"	No. in House	No. Vacc.	No. in House	No. Vacc.	No. in House	No. Vacc.
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SURVEY FORM FOR

Towns and Villages with Less than 5,000 Population (Continuation Sheet)

	Date(s) of Survey										
	0-4 years of age				5-14 vea	rs of age			The same		
No.	No. in House	No. Vacc.	No. Inspected	No. with "Take"	No. in House	No. Vacc.	No. in	No. Vacc.	No. in House	No. Vacc.	
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SMALLPOX ERADICATION PROGRAM

SURVEY FORM FOR

Towns and Cities over 5,000 Population

Fown or City	Estimated Population
Medical District	Estimated No. of Blocks
Date Vaccinated	Date(s) of Survey

5 6 7 8 5 6 7 8 <t< th=""><th></th><th colspan="3">0-4 years of age</th><th colspan="2">5-14 years of age</th><th colspan="2">15-44 years of age</th><th colspan="2">45+ years of age</th></t<>		0-4 years of age			5-14 years of age		15-44 years of age		45+ years of age		
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A. Introduction

The primary objective of the West African program is smallpox eradication. Surveillance is essential to the success of the program since the term, eradication, implies that the number of indigenous cases of smallpox is "0" or, if imported cases have resulted in circumscribed outbreaks, the latter have been quickly terminated. The ultimate success of the program, therefore, is measured <u>not</u> in terms of the proportion of the population vaccinated but in terms of cases of smallpox. However extensive the vaccination campaign, however accurately assessed, a country with an inadequate system for surveillance will be little more knowledgable regarding the actual success of its efforts than a blind man operating a panel of light switches.

Surveillance represents a great deal more than case reporting alone. It is composed of several components:

- The routine, systematic collection of data, amplified appropriately by special field investigations and studies.
- The analysis and interpretation of reported data and studies on a concurrent basis.
- 3. The initiation of appropriate definitive action including field investigation, epidemic control, modification of operational campaign procedures, recommendations regarding vaccination, etc.
- 4. Widespread dissemination of the compiled and interpreted data to principal reporting sources and to others concerned with disease control activities.

The effort and cost expended in establishing a surveillance system should more than repay itself during both the mass campaign and maintenance phases. For example, the persistence of cases in areas where programs have been completed may indicate that the vaccine was impotent, or that significant elements of the population were missed; corrective measures can be promptly taken in the course of the program. In Peru, failure to establish a surveillance program following successful

eradication efforts, resulted in reintroduction and reestablishment of the disease prior to recognition. Repeat country-wide vaccination programs had to be instituted. Surveillance systems could have been established and maintained at a fraction of the additional costs subsequently incurred.

The absolute necessity for an adequate surveillance system as an integral part of the eradication program is belabored intentionally. While appreciating the need to conduct systematic mass vaccination programs, health officials do not always comprehend the need for, or importance of, a well-established and maintained system for smallpox surveillance.

The concept of surveillance as an operational unity is in its infancy although the need for an importance of surveillance is increasingly appreciated. At present, the World Health Organization has initiated plans to develop surveillance systems for various diseases on national, regional and global bases. Only a few countries, however, now have what could be termed effective surveillance systems; a number are in the process of modifying present administrative and operational procedures to achieve this objective.

Health officials in West Africa are best acquainted with the practices of health administration in France and England. A word regarding surveillance in these countries may be helpful. Surveillance activities in England are fragmented and differently oriented than in the USA. Routine disease reports are directed to the Ministry of Health; field investigations, when requested, are carried out by an independent entity, the Public Health Laboratory Service; disease control and investigative activities are highly decentralized to local health authorities.

Mechanisms for close, routine communication between these separate organizations have not been developed. In France, epidemiology itself has only recently begun to receive attention. Although there is an established system for routine reporting of specified diseases, continuing interpretive analyses of data and field investigations are limited and, as in England, disease control activities are highly decentralized.

These various considerations should be kept in mind for, however simple and straightforward surveillance may appear both conceptually and administratively, it has been the CDC experience that its nature, function and potential contribution has been most difficult to grasp for those in the practice of public health, academic or clinical medicine.

B. Definition and Principles of Execution of a Surveillance System

Surveillance, as pointed out above, consists of several interrelated basic components, each of which needs to be interwoven with the others.

- The routine, systematic collection of data, amplified appropriately by special field investigations and studies.
 - 2. The analysis and interpretation of reported data and studies on a concurrent basis.
- 3. The initiation of appropriate definitive action including field investigation, epidemic control, modification of operational campaign procedures, recommendations regarding vaccination, etc.
- 4. Widespread dissemination of the compiled and interpreted data to principal reporting sources and to others concerned with disease control activities.

1. The routine, systematic collection of data

The basis of the surveillance system is the routine, systematic reporting of individual cases of disease, provided through established notification systems. To facilitate prompt reporting, clinical diagnoses of cases are generally relied upon with subsequent modification of diagnoses, as appropriate, when laboratory work is done. Reporting sources may include hospitals, medical aid posts, physicians in practice, prospection teams, etc.

Before the inception of a surveillance program, under-reporting of cases is a common problem, especially when the disease is prevalent. Many persons do not reach medical attention and thus do not come to recognition; others submit to medical care but, for one reason or another, are not reported.

When special attention is focused on a disease, as in the instance of an eradication program, an immediate improvement in reporting is customary but this is neither sustained nor is it maximal without a special stimulus on the part of the national and local health authorities. Several steps may be taken which have been found helpful:

- a) Motivation of units to report A response from central and/or local health authorities which indicates that disease reports are being used has the most pronounced effect in stimulating reporting. Distribution of a surveillance report with compiled and interpreted data has, in the CDC experience, sparked a notable improvement in reporting. Direct query regarding submitted data or active field investigation or control activities resulting from reports submitted represents an even better stimulus.
- b) Focus, for reporting purposes, on a limited number of diseases Ideally, reports of cases should be solicited for a limited, designated group of diseases for which there is an obviously valid justification. This would include diseases for which some definitive preventive measures might be taken if an increased incidence occurred, and for diseases for which preventive measures are contemplated and for which some idea of incidence in different areas would be helpful. In some countries, reports are frequently requested for as many as 150 diagnostic categories of disease. It is not possible to motivate individuals to report on each and every one of these categories even if they had the time and inclination to do so. The data obtained will reflect current fashion and personal preference with preferential reporting of some diseases in one area and other diseases in other areas "nation-wide" data, however interpreted, have little meaning in these circumstances.

For diseases for which reports are requested, the amount of information solicited should be kept to an absolute minimum consistent with "need to know". A report requiring more than 2 to 3 minutes to complete is, almost certainly, too detailed. In brief, reports must be simple, the questions asked must be unambiguous, and they must require a minimum of time for completion.

- c) Regularity of reports For concurrent appraisal of a disease problem in a country, particularly when immediate preventive measures may be indicated, reports must be submitted on a frequent, regular basis. When reports are not received, prompt followup serves as a useful goad and, further, demonstrates an interest on the part of higher authority in receiving these reports. If no cases are observed during the fixed time period, "negative" reports noting this fact should be sent. Receipt of reports, for example, from 60 of 100 reporting centers does not mean the other 40 have had no cases. Acceptance of "no report" as being the equivalent of "no cases" has permitted countless "brush fire" outbreaks to mature into full-fledged "forest fires".
- d) Number of reporting sites With more reporting sites, it is evident that the potential for more complete reporting is greater. One would like to have routine, systematic reporting from every hospital, medical aid post, prospection team, and other medical facility throughout a country. Such complete participation can be achieved only with time, patience, cajolery, flattery, etc., but clearly this should be a primary objective for a good surveillance program. Although use of schools, industries, village leaders, etc. as reporting points has often been advocated, rarely can non-medical individuals at these sites be depended upon to report regularly and accurately. The expenditure of effort to actuate such a system is considerable; in isolated instances, such systems have been made to work but rarely is the "juice worth the squeeze". The overall surveillance

scheme, however, may be strengthened by approaching such groups and asking that they notify the existence of cases to a proximate medical site so that this facility might appraise the case or cases and report them.

Rarely, however, have voluntary, lay groups been found sufficiently effective or reliable over a continuing period as primary sources of data.

As a maxim, it is important that the clinical diagnoses of cases should be accepted <u>until proved otherwise</u>. Some health authorities have disparaged "clinical" reports arguing that clinical impressions are meaningless unless confirmed by the laboratory. For some diseases, this is true but for smallpox, we are fortunate in that a reasonably high degree of accuracy in diagnosis is possible. Unfortunately, when laboratory confirmation is required, a long lag in reporting is introduced due to delays in collecting specimens, performing tests, etc. When laboratory reports are finally received, local authorities frequently forget that the cases have not been reported or ignore reporting them, considering them to be "ancient history". It is far better to have an initial provisional report which is subject to modification as a result of laboratory testing, than to have no report at all.

Given a systematized, routine data reporting system, other sources of information may be sought to insure its relative completeness and to amplify and define the information. Newspapers, radio, rumor, political party structure, etc. may all at one time or another provide information not otherwise obtained. Reports from such sources should be solicited. Field investigations, serological surveys, interview surveys, etc. should be used appropriately to further dissect the problem. These are not, however, substitutes for systematic data collection but supplements to a well established system.

2. The concurrent analysis and interpretation of reported data and investigations

The concurrent analysis and interpretation of reported data and field investigations is a more sophisticated function and should generally be carried out by a central unit competent to do this. In many, perhaps most countries, reported cases of disease are directed to a statistical unit often physically and administratively separate from the operating disease control or epidemiological unit. (Until 1960, such was the case in the U.S.) These units frequently are delayed weeks or months in compiling data and generally have no specific epidemiological competency to interpret or to follow up promptly on the information obtained. Since the initiation of appropriate action, whether field investigations or epidemic control measures, is an integral part of surveillance, concurrent analysis and interpretation of reported data in the context of the total program is critical, thus, ideally and practically the unit concerned with the statistical compilation of morbidity data should be an intrinsic part of the disease control and/or epidemiological unit and immediately responsible to it.

3. The initiation of appropriate definitive action

exercise unless some definitive actions are initiated as a result of information obtained. Field investigations of outbreaks or sporadic cases, especially after mass vaccination campaigns, are important to ascertain the cause for such outbreaks or cases: e.g. Were nomads responsible? Was there some significant segment of the population which was inadequately vaccinated, e.g. field workers, adult women, etc.? Was the vaccine potent? Determination of the epidemiological factors concerned may serve to alter procedures and approaches to be employed in the continuing mass campaign.

Additionally, prompt control of epidemics through mass vaccination prior to systematic, planned mass campaigns in an area will serve to reduce the overall reservoir of circulating virus and will facilitate the achievement of eradication.

The extent and type of action indicated is, of course, dictated by the relative prevalence of the disease, factors relating to the spread of the disease, the practicability of initiating control procedures, relative

priorities in workload, etc. It is difficult, however, to conceive of an effective surveillance program in which <u>no</u> definitive actions resulted in consequence of disease reporting and data analysis. As a general rule, the more activity generated, the more responsive will be the primary reporting sources, the more adequate and meaningful the data, and the more effective the program as a whole.

4. Distribution of data and interpretive material to all concerned with disease control activities

This area is the most frequently overlooked component of the surveillance complex. Yet this component of surveillance, well conducted, can be the single most important action in motivating disease reporting, educating those concerned with disease prevention, and stimulating disease investigation and control. The reports, if they are to be effective, must include narrative which serves to dissect and interpret the meaning of the statistical tables normally included. Nothing is quite so meaningless or of so little educative value as a series of statistical tables without interpretation or discussion. Such reports commonly are discarded for few receiving them will have a sufficiently comprehensive knowledge of programs, activities and diseases processes to draw reasonable conclusions from the "raw data" presented.

Suppression of data on the part of nervous or sensitive public health officials is a not uncommon tendency. It is to be deplored. With considerable experience in this area, it can be said that almost invariably a report which provides a concurrent, accurate and complete presentation of the facts of an outbreak or disease problem and a description of the control procedures set in motion has the effect of reducing public anxiety (if this be a problem), by demonstrating to all concerned that the health jurisdiction in question is knowledgable of the problem and "on top" of it. The prestige of the health authority is almost inevitably heightened by this action rather than the reverse.

C. Application of Surveillance to the African Smallpox Program

The development and effective integration of a surveillance program within the context of an established health structure is a time-consuming task; the difficulties in undertaking this should not be under-estimated. Since each national health structure differs at least to some degree from all others, no simple "cookbook" formula can be provided for establishing an adequate surveillance program nor should it be presumed that there is an ideal, ultimate pattern. It is anticipated that, in each country, techniques and practices will differ to a greater or lesser degree, with varying strengths and weaknesses in each of the programs.

The following provides general guidance for developing and establishing a surveillance scheme and sets forth the specifics regarding data which, at this time, are believed necessary for the Regional Project Office to carry out effectively its coordinative role on a regional basis.

1. Definition of a Case

For purposes of the basic reporting system, it is important to accept as "cases" all illnesses which are clinically suspect as being smallpox and to encourage, if anything, over-diagnosis rather than the reverse. Subsequent investigation may indicate another diagnosis and may require that the notification be amended. For maximum sensitivity, however, especially in this program in which the goal is cessation of <u>all</u> cases, it is better to err on the side of over-reporting than of under-reporting from the inception of the program.

In some countries, smallpox (variola major) and alastrim (variola minor) are separately reported and the latter is not considered to be "true" smallpox. This is a serious error. Given a single case or even a small group of cases, it is impossible for the most capable clinicians to differentiate these two variants unless the disease is fulminating (e.g., hemorrhagic smallpox) in which instance variola major is immediately suspect. Even with a good laboratory, differentiation of these two variants is questionable. It is granted that with an

epidemic involving many cases in unvaccinated persons and a very low casefatality rate, the designation "variola minor" can be assumed. However, from
the standpoint of eradication, the two variants must be regarded as one disease
and reported simply as "smallpox".

2. Development of Reporting Centers

As previously described, primary effort should be directed toward securing regular reports from as many medical and paramedical units as possible throughout the country.

In developing this phase of the program, all units which potentially may provide reports and those currently providing reports should be identified early in the planning phase to ascertain the present and potential geographical completeness of the system. If there are significant areas lacking in detection sites, special measures might eventually be required to secure reporting in these areas. School masters, village chiefs, special reconnaissance surveys, etc., might have to be relied on. In most countries, however, it is unlikely that many ancillary sites will need to be developed.

The development of dependable and reliable reporting from the various sites is a lengthy and continuing process. A formal government decree emphasizing that smallpox is a mandatory, reportable disease and that all cases must be notified may be helpful and may serve as a reminder. Such a requirement, however, now exists in virtually every country (through International Sanitary Regulations agreements). Obviously, this has been no guarantee that cases will be reported. Motivation of primary reporting units is the real key to success in a surveillance scheme but this will take time and patience and will require considerable wit and imagination.

Since the development of an effective reporting network is a time-consuming task, it is well to initiate steps to improve or develop it from the inception of the vaccination program. First efforts might be focused on the more major medical units (e.g., hospitals) and other units already reporting routinely or

occasionally, to encourage them to report regularly and more completely. In the course of the systematic, mass vaccination programs, field investigations, etc., other units may gradually be drawn into the complex. Fully two years of continuing work is probably minimal for the development of an adequate surveillance reporting network.

Transmission of data

In most countries, reports of cases of various diseases are normally transmitted to higher authority on some regular basis, e.g. weekly, bi-weekly or monthly. For smallpox, telegraphic notification of cases is more or less a routine in some countries. Although telegraphic reporting may be useful in countries where smallpox has reached negligible levels, such is not required within the country according to International Sanitary Regulations (Article 3):

"Each health administration (i.e. the governmental authority responsible over the whole of the territory to which the Regulations apply) shall notify the Organization by telegram within 24 hours of its being informed that a local area has become an infected local area." Note, however, that telegraphic notification to WHO regarding smallpox cases by national authorities is requisite.

In adjudging the desirable frequency and rapidity of reporting, two principal pal factors must be taken into account.

a) Status of eradication - For a country without smallpox or with few cases reported, the need for prompt, assured field investigations and the institution of control measures call for the most rapid communication possible.

In an endemic country with large numbers of cases occurring in many areas, telegraphic reporting generally offers little advantage. Under such circumstances, control activities generally must be limited to efforts to prevent the spread of epidemics. Such epidemics do not develop explosively, in a matter of days; they take weeks to evolve. Thus, weekly notification may be quite sufficient.

b) Current pattern of reporting - In the development of the reporting system for smallpox, it is important that the existent reporting structure be carefully studied with respect to its strengths and weaknesses, both in terms of its prescribed methods and the ways in which it functions in practice.

Most countries provide for regular reporting of various diseases from the medical posts. Some reports are filed on a weekly basis, some on a biweekly basis and some on a monthly basis, or even less frequently. If reports routinely are being made on a weekly or biweekly basis, it may be best to adhere to present administrative custom, at least until the numbers of smallpox cases decline to low levels. If reports of smallpox are provided less frequently than every two weeks, the potential for effective response is significantly compromised; during the time interval between the first detection of cases and the initiation of action a major epidemic could develop. What might have been controlled as a "brush fire" emerges as an uncontrollable "conflagration". Thus, at no time are reporting intervals of greater than two weeks to be recommended.

4. Cross-notification

When investigation reveals that the cases investigated had their origin in another health jurisdiction, or constitute a threat to another area because of the movement of possibly infected persons, it is important that the responsible authorities in the affected health jurisdiction be notified. A mechanism for such cross-notification should be developed in each country, one which permits prompt notification and assures prompt action when all involved areas are within the same country. When two or more countries are involved, international notification becomes necessary. It is to be hoped that an efficient means for effecting this can be developed among the countries in the 19-country region. The Regional Project Office in Lagos can assist in this activity. The information transmitted should be brief but complete, including:

name, age, sex and other personal identification; locality(ies) involved; dates; pertinent information concerning nature of exposure or threatened exposure.

5. Type of data to be transmitted

In surveillance programs, it has been found helpful, if not essential, to receive information which records not only the existence of a case but also simple epidemiological data pertaining to the case such as geographic location, age, sex, and date of onset. Seasonal and geographical relationships can thus be defined; concentrations of cases within particular age groups or among males or females, for example, may signal the need for definitive studies of the epidemiological situation. Simple data such as these are readily available at the reporting source and may be quickly and simply recorded in the form of a "line listing" such as is illustrated in Figure 1.

In the smaller countries, including many of those in West Africa, these "line listing" reports might most efficiently be submitted directly to the national headquarters. In larger endemic countries, the "line listings" might be submitted to an intermediate health jurisdiction which could insure that appropriate investigative or control procedures have been undertaken. Comprehensive analyses of data might be undertaken at this administrative level as, for example, at the Regional Provinces level in Nigeria, or forwarded to the national program headquarters.

6. Recording of data

At the level where analyses are to be undertaken on a continuing basis, a great many different methods of recording the data may be useful. Based on experience at CDC, use of at least four different techniques for a continuing analysis can be recommended.

a) A record of sites reporting

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C	х	x	x		x				x		45	
D		x			x						10	
Total	3	3	3	1	4				3		10 - Ju	

A simple check sheet to indicate which sites have reported and which have not (to permit followup query) would be a simple approach to assess completeness of reporting by site.

b) A record of numbers of cases by week by geographic area

A tabulation sheet used at CDC to record numbers of cases of a disease by week for a single geographic area is shown in Figure 2. A separate sheet normally would be used for each geographic area (e.g. Secteur, Medical District, etc.) Note that provision is made for entering corrections and corrected weekly totals. A sheet such as this permits rapid assessment of the smallpox problem by area by time period.

c) A spot or pin map designating geographic locale of cases

A wall-mounted "pin map" or simple "spot map", each case being represented by a dot or pin, further helps to define geographic concentrations.

d) A variety of other systems for continuing analysis by age, sex, and area may be constructed from weekly line listings of cases dependent on need, time and available personnel. One such example is portrayed below:

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7. Reporting of data to Regional Project Office (or in Nigeria to the National Program)

A report of smallpox cases is required every four weeks for regional coordination of the program (Figure 3). This must include total cases by age and sex, as well as by province or other reporting segment. A summary of the number of units which provided reports during this time period, as well as the total number of established reporting sites is also requested, to provide a rough indication of the completeness of reporting.

The principal emphasis for reporting has been placed on smallpox since this program is directed toward eradication. However, it is also necessary to have such data as are vailable pertaining to the occurrence of measles (Figure 4). At a later date, it may prove feasible and worthwhile to obtain more detailed reports regarding measles. At present, however, only minimal already—available data are requested.

Copies of these reports may be requested by regional organizations (OCCGE and OCEAC) and should, of course, be sent by national health authorities.

Further discussions will be held with these Organizations to insure maximum coordination with respect to reporting.

8. Preparation of surveillance reports

The importance of disseminating reports on a regular basis to reporting sites and to others concerned with disease control has been commented upon. Initially, such reports might be prepared on a quarterly basis and, if felt desirable, increased in frequency to perhaps a monthly or, in special circumstances, to a weekly basis. With some surveillance programs at CDC, reports are scheduled at regular intervals but issued more frequently during epidemic periods.

Various formats might be employed for the report and various types of information included. Routinely, it would seem well to include an overall summary of the disease situation, a discussion and interpretation of various salient epidemiological characteristics, reports of outbreak investigations and basic tables of current data showing cases by week and geographical segment. Progress notes and reports regarding the vaccination campaign might be included as well as a discussion of plans or policies with respect to the program itself.

Surveillance reports of various types prepared at CDC for U.S. programs will be sent to you routinely as a sample of various means for presentation of surveillance data.

9. Intensity of surveillance and field investigations

In countries with a high endemic occurrence of disease, field investigation activities may focus on comparatively few of the many outbreaks. As systematic vaccination programs progress, the importance of small outbreaks and individual cases becomes increasingly important. As the numbers of cases diminish, the field investigations and control procedures should be instigated for an increasing proportion and, ultimately, for all cases, to ascertain possible weaknesses in the vaccination program and to institute containment measures. Laboratory assessment of cases becomes of increasing importance. When mass programs have covered the entire country or in countries or areas where smallpox is now almost completely absent, each case becomes an "emergency". Telegraphic reporting,

prompt investigation including laboratory stwdy, and containment measures are called for.

When field investigations of outbreaks or cases are called for, forms such as shown in Figures 5 and 6 may be useful in the systematic collection of data to permit a definitive diagnosis to be made. The form shown as Figure 5 includes a great deal more clinical information. It is based on an old CDC National Smallpox Surveillance form designed to assist the investigator in collecting necessary clinical data to make a differential diagnosis. The second form (Figure 6) has been simplified. It was designed for the African program and focuses on major items of epidemiological significance.

10. A schematic outline for the development of a smallpox surveillance scheme

In the development of a smallpox surveillance program, several stages in the type of activity can be visualized as the incidence of smallpox declines. These phases, really parts of a continuum, might be defined for purposes of discussion as follows:

- PHASE I Endemic areas with a sustained or frequent high incidence of smallpox as appraised either by official reports or educated estimates. This would include all countries with a rate of perhaps 1.0 or 2.0 cases or more per 100,000 population.
- PHASE II Countries with a low continuing incidence of smallpox.
- PHASE III Areas rendered non-endemic by systematic vaccination.

 (No country or subdivision should be classified as Phase III unless and until it has been covered by the attack phase of systematic mass vaccination under the present program, and unless incidence has been reduced essentially to "0".)

A summary of activities and duties appropriate to these phases in the eradication program is indicated in the following:

Reporting

Emphasis on principal medical units to obtain regular reports. Progressive extension to include all medical and paramedical units.

Extension of surveillance network to insure that detection sites exist in all parts of country and that reports are regularly submitted. Some telegraphic reporting of cases. As in Phase II. All cases reported telegraphically.

Field Investigation Investigation of

Investigation of significant epidemics or epidemics in unusual areas as time permits.

All outbreaks promptly investigated by competent epidemiological authority. Cases promptly investigated by same or at intermediate health jurisdictions. Case investigation forms submitted for every case.

Each case an "emergency". All cases promptly and routinely investigated by competent epidemiological authority.

Control procedures Special units to

Special units to undertake epidemic control as necessary.

Prompt control procedures for each case and outbreak by central or intermediate health authority. Prompt control procedures with central authority participation. Identification, vaccination and, if necessary, isolation of contacts

Laboratory study of Cases

Only in special circumstances, usually for research purposes.

Specimens to be obtained from each isolated case and representative samples from outbreaks.

Every case to receive laboratory study.

Instructions for WEEKLY SURVEILLANCE OF SMALLPOX CASES

1. Made by:

Designated Reporting Centers

2. Transmittal:

The notification form should be sent by mail every week to the Senior Medical Officer in your District for transmittal to:

Chief, National Smallpox Eradication Program (Address)

3. Deadline for transmitting report: The weekly notification form must be sent at the close of the reporting week (Saturday) and not later than Tuesday afternoon of the following week. The weekly report must be transmitted even if there were no cases reported during the preceding week.

4. Forms:

Ten cases of smallpox may be line-listed on each weekly surveillance form. If there are more than 10 cases, use a second form, etc. All requested information is to be shown on the form for each case. If all the information is not available, at the time of notification, fill in whatever information is available. An incomplete report is better than no report at all.

5. How reports are used: The weekly surveillance reports are consolidated each week at the Ministry of Health so that a Smallpox Surveil-lance Report can be prepared monthly and distributed. The weekly reported case data are basic to the determination of current trends in the incidence of smallpox and to the detection and control of smallpox outbreaks.

WEEKLY SURVEILLANCE OF SMALLPOX CASES*

181	ing Unit: _	(Name)		(Medical District)					
] Ch	eck this box	if there were n	o cases this week						
No.	Name	Father's Name	Town or Village	Province	Age	Sex	Date of On:	Day	
10 8	ola mia su		1 gay by 1311ac	Diser = D					
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o Hol			The same feature			+			
Comme		note of any of the province or coun	ne above cases thatry):	at may have	cont	racted	d this disea	se in	
Repor	rting Officer		Title				Date		

^{* (}See Instructions on Reverse Side)

Wee	ks Ending		- funda-		\$ 1,18		s Ending				
	urday		Correc-	Correct	Cumula-		rday		Correc-	Correct	Cumula
	1966	Weekly	tions	Weekly	Weekly tive		1967	Weekly		Weekly	tive
1	Jan. 8					1	Jan. 7				
2	15					2	14				
3	22					3	21				
4	29					4	28				
5	Feb. 5					5	Feb. 4				
6	12					6	11				
7	19 26			-		7	18 25			0.5	
9	Mar. 5			-	-	9	Mar. 4				
10	12		-	1		10	11				-
11	19			1	-	11	18				
12	26					12	25				
13	Apr. 2					13	Apr. 1				
14	9					14	8				
15	16					15	15				
16	23			1		16	22				
17	30				-	17	29				
18	May 7					18	May 6				
19	14			-		19	13				
20	21 28			+	-	20	20				-
22	June 4			-	-	21	27				
23	11			-		23	June 3				-
24	18					24	17				
25	25	C TO STATE OF THE PARTY OF THE		1		25	24				-
26	July 2					26	July 1				
27	9					27	8		THE STATE OF		
28	16					28	15		Tona and the same		
29	23					29	22				
30	30					30	29				
31	Aug. 6					31	Aug. 5				
32	13				-	32	12				
33	20					33	19				-
34	27 Sept. 3			-	-	34	26				
36	Sept. 3			-	-	35 36	Sept. 2		-		-
37	17			+	-	37	16			-	
38	24					38	23				
39	Oct. 1			1		39	30				
40	8					40	Oct. 7				
41	15					41	14				
42	22		BATTON			42	21				
43	29				Real Test	43	28				
44							Nov. 4				
45						45	11				(4)
46	19		-	-		46	18				
47					-	47	25				-
48			-	-	-	48	Dec. 2				-
50				+		50	16		-		
51				-	1	51	23				
52				1		52				†	1
						1					
FIRE											
	Total					I	Total				

Instructions for / MONTHLY SMALLPOX MORBIDITY REPORT

- 1. Made by: Smallpox Eradication Program Director in each of the 19 countries participating in the West African Smallpox Eradication Program.
- 2. Transmittal: The monthly smallpox morbidity report should be transmitted by mail every four weeks to:

Chief, Regional Project Office

3. Deadline for transmitting report: The "monthly" report will cover the preceding 4 reporting weeks. Since there are 52 weeks in one year, there will be 13 "monthly" reports during each year, each report covering a 4-week period. The 13 "monthly" reports will cover the 4-week periods as shown below:

Monthly Report	Includes Week	Include (Wee	s Four				g:
No.	Nos.	Month	1966	1967	1968	1969	1970
1	1-4	January:	29	28	27	25	31
2	5-8	February:	26	25	24	22	28
3	9-12	March:	26	25	23	22	28
4	13-16	April:	23	- 22	20	19	25
5	17-20	May:	21	20	18	17	23
6	21-24	June:	18	17	15	14	20
7	25-28	July:	16	15	13	12	18
8	29-32	August:	13	12	10	9	15
9	33-36	September:	10	9	7	6	12
10	37-40	October:	8	7	5	4	10
11	41-44	November:	5	4	2	1	7
12	45-48	Nov/Dec.:	/3	/2	30/	29/	/5
13	49-52	Dec/Jan.:	31/	30/	28/	/3*	/2

^{*} There are 53 weeks in 1969 and the week ending January 3, 1970 should be included in the last four-week period of 1969.

This 'monthly" report should be sent to the Regional Office in Lagos as soon as possible after the close of the reporting period. The "monthly" reports will be consolidated in Lagos so that a monthly Smallpox Surveillance Report can be prepared and distributed throughout the 19 countries.

MONTHLY SMALLPOX MORBIDITY REPORT* WEST AFRICA SMALLPOX ERADICATION PROGRAM

Male	Female	Unk.	Total	
+				
CONTRACTOR OF THE PARTY OF				
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	a langer	1 7 7 1 7 1 1 1 1	DE HELL	
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1200 100				
			17.6	
11000	1 No.			
				-
A MACI			7 30	
		ographic Distribut	ographic Distribution of Sma	ographic Distribution of Smallpox Case

* The reporting period is the four-week period ending on Saturday as shown on the reverse of this form. (See Instructions on

Reverse Side.)

Instructions for MONTHLY MEASLES MORBIDITY REPORT

anger and the state of the second

1. Made by: Smallpox Eradication Program Director in each of the 19

countries participating in the West African Smallpox Eradication

Program.

2. Transmittal: The monthly measles morbidity report should be transmitted by mail every month to:

Chief, Regional Project Office

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DHEW, PHS, CDC

FIGURE 4

MONTHLY MEASLES MORBIDITY REPORT* WEST AFRICA SMALLPOX ERADICATION PROGRAM

Country	Month

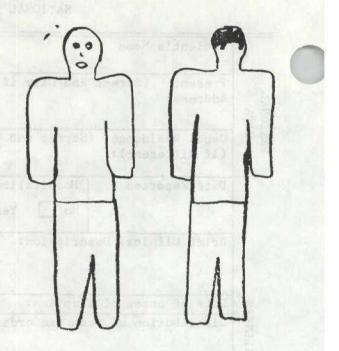
Measles Cases and Deaths by Age

Age	No. of Cases	No. of Deaths
<1		
1		
2		
3		
4		
5-9		
10+		
Unk.		
TOTAL	a House	

^{*} The measles report should be derived from whatever reporting procedure is in current use.

FIGURE 5 NATIONAL SMALLPOX SURVEILLANCE CASE RECORD

1	Patient's Name				Age	Sex	Tribe
TA	Present (Street an Address:	d City if ur	ban area)	(Village	and o	district	if rural area)
DATA	Usual Residence (St (If different):	reet and Cit	y if urban an	cea) (Villa	ge and	distri	ct if rural are
		ospitalized:		l Location)		Date	of 1st symptoms
	Brief Clinical Descr	iption:	(Symptoms a	and signs, m	ax imur	n temper	ature, etc.)
SS	Date of onset of eru	ption:	1	Ouration of	erupt	ion:	days
ILLINESS	Distribution of rash	(in order o	f appearance				
PRESENT I	Sketch distribution	ions at heig	ht of eruption	on were:			occur in
PR	PERSONAL PROPERTY OF THE PROPE	tular 🔲	Hemorrhagio		Yes	cessive o	mana warben
		p-Seated _	inofs earlibr		Out	come of	and the second second
	CONTRACTOR SPECIAL PROPERTY OF THE PROPERTY OF	tilocular	a al xoglinio May qaqoly i	to jonno e		Recovered	
2 1	Earliest vaccination	date	l N	lost recent	vaccin	nation d	ate
HISTORY	Has patient ever had Smallpox? No Chickenpox? No Skin allergy or chro	Yes, Date	Are th	ere residua			
LION	Was patient recently a case of Smallpox a case of Chickenp a recently vaccina Other (specify)	? ox?	(If yes, g	(ive dates,	place	, and to	whom exposed)
INFORMATION	Travel away from usu 12 to 14 days) prior	to onset:	di serrepe		evi.		100081000
TESTS	Specimen	Date Collected	Test Performed	Results	Nar	ne and le	ocation of Labo
LS	Vesicle fluid or pus			THE PARTY OF THE P		3 44 14	Jane
TESTS	Crusts	+	-		-		
H	Other (Specify)	following -	nont (11)	In1	- P		W- 4
5	Date of vaccination	rollowing pro	esent lliness	Kesul	: Pr	imary	Major Equivo
180							
	Investigator's Name			Title			XIII JA SEE JA JA SEE
PRAISAL	Investigator's Name Date(s) of investiga Investigator's impre		. 0-11		- P-	h)c= =	Not Smallpox [



Smallpox Diagnosis: Classical smallpox is a disease distinguished by exceedingly severe Syptems signs and symptoms and an extensive pustular eruption. However, previous vaccination may modify the severity of the clinical and eruptive features of the disease, and mild forms of the disease occasionally are seen. Therefore, it is often quite difficult to arrive at a definite diagnosis from clinical findings alone.

<u>Prodromes</u>: Typically, the onset of smallpox is marked with severe headache, backache, malaise and chills. The temperature may reach 105. However, previous vaccination may modily the severity of signs and symptoms. Eruption usually follows prodromes by 2-4 days.

Eruption: The lesions characteristically progress from macules to pustules, usually reaching the full-blown stage by the 6th day of rash. The eruption begins on the face, neck, upper chest, arms and hands, and is typically most severe in these exposed areas. The lesions, when fully developed, are yellow, split-pea sized, firm, deep-seated, umbilicated, and surrounded by a faint red border. When the lesions are accidentally ruptured, pus exudes but they do not completely collapse (i.e., they are multilocular). The lesions are all in the same stage of development, not in successive stages, nor are they surrounded by a wide areola, as in chickenpox.

<u>History</u>: Certain other eruptive disorders may be mistaken for smallpox. The commonest is chickenpox. In addition to chickenpox, syphilis and disseminated vaccinia should be considered.

Contacts: It would have been fairly apparent if one of the every-day contacts of the patient had been the source of smallpox; therefore, inquire carefully into the outside contacts during the 3-week period (especially 12 to 14 days) prior to onset.

Laboratory Tests: The virus may be demonstrated in smears or isolated from vesicle (or pustule) fluid or from crusts.

Following recovery, and unless contra-indicated, the patient should be vaccinated. A primary or accelerated reaction would provide very strong evidence against a diagnosis of smallpox.

ĽA	Province Date Case	100		A AMPAN	SMALLPOX CASE,	The state of the state of all the state of the state of		GRAM			
N DATA	Notified:										
ATIC	Name				Father's Name		Age	Sex	Tribe		
IDENTIFICATION	Address				Village or City		Count	County, District			
IDEN	Source of Case F			Inve	estigation of Oth	er Case	Occup	pation			
	Date of Onset of Rash: Hospitalized:	Yes No	Va	Neve	er Vaccinated		on if Ever				
SS	Outcome of Case: Recovered Primary Vaccination or Revaccination Still Sick Died Scar Present: Yes No Known Contact with Smallpox Case 7 to 17 Days Prior to Illness:										
ILLINESS	-	Contact's			to 17 Days Pric	Date of	Place of	of Cont	act		
	Name		Age	Sex	Same Household	Contact	Village (Control of the last of the las			
PRESENT	1.				Yes No						
QN	2.			-	Yes No						
DRY A	3.				Yes No						
HISTORY	4.	7211	6	There	Weeks Prior to	Illness up	til Time e	f Truce	tigation		
H	The second secon	nts of T			Means of Trans						
			□ No		Yes - Date Coll	lected	Re	sults:			
LAB	Specimens Collection Investigator's		_	Case		Did yo	u Vaccinat	e	- C- 112C		
Н.	Investigator's Smallpox	Impress	ion of	Case				- personal	No		
APPRAISAL LAB	Investigator's	Impress	ion of		x Uncertain		ts? Ye	- personal	No		

TECHNICAL CONSIDERATIONS

I. MEASLES VACCINES

CONTENTS

- A. Live Virus Vaccine Types
- B. Use to Date in Africa

Edmonston B strain vaccine Schwarz strain vaccine Beckenham strain vaccine

- C. Production Medium
- D. Clinical Response to Vaccination
 - 1. Fever and Rash
 - 2. Other Clinical Findings
- E. Antibody Response and Protective Efficacy
 - 1. Antibody Response
 - 2. Protection against Natural Disease
 - Response to Challenge of Children with Low Antibody Titers
 Summary
- F. Age at Vaccination
- G. Vaccination during an Epidemic
- H. Administration of Measles Vaccines Simultaneously with Other Live Virus Vaccines
- I. Vaccine Stability
 - 1. Desiccated Vaccine
 - 2. Reconstituted Vaccine

 - Effect of Light
 Disposal of Vaccine at End of Day

I. MEASLES VACCINES

A. Live Virus Vaccine Types

There are two types of live virus measles vaccine licensed for use in the U.S.A.:

Usual designation	Alternate designations	Commercial names	Company
Edmonston B strain vaccine	Enders Edmonston B strain vaccine	Lyovac Rubeovax	Merck, Sharp & Dohme
	or		
	Attenuated vaccine	Measles Virus Vaccine, Live Attenuated (Chick Embryo)	Eli Lilly
		grange syn de lik	
		Measles Virus	Phillips-
		Vaccine, Live, Attenuated	Roxanne and
		(Canine kidney)	Parke-Davis
		Pfizer-Vax- Measles-L	Pfizer
Schwarz strain vaccine	Further atten- uated vaccine	Lirugen	Pitman-Moore

In England, two types of vaccine are produced: (1) Schwarz strain vaccine (produced by Glaxo) and (2) Beckenham strain vaccine (produced by Burroughs-Wellcome). The latter vaccine has characteristics similar to the Schwarz strain vaccine. In France, the Merieux Company in Lyons has begun production of Schwarz strain vaccine.

B. Use to date in Africa

The vaccines noted above include all known to have been used or tested in West Africa.

Edmonston B strain vaccine - Through June, 1965, this was the only vaccine used in mass programs in West Africa. During FY 66 (July 1965-June 1966), Edmonston B strain vaccine was used in extensive programs in Chad and Cameroon and some was used in Upper Volta. Field evaluations have been conducted in the Ibadan area in Nigeria during the past five years and, in FY 66, in Enugu (Merck, Sharp and Dohme vaccine) and in Lagos (Pfizer vaccine).

Schwarz strain vaccine - Prior to July 1965, limited trials were carried out in the Ibadan area and possibly also in Dakar. During FY 66, this vaccine was used in mass programs in Mauritania, Mali, Niger, Guinea, Ivory Coast, Dahomey, Togo, and in Upper Volta (where some Edmonston B strain vaccine also was used).

Beckenham strain vaccine - Limited trials have been carried out in Nigeria during the past several years.

C. Production medium

All of the vaccines described above are produced in chick embryo cell culture except for the Edmonston B strain vaccine produced by Phillips-Roxanne (marketed both by Phillips-Roxanne and Parke-Davis) which is propagated in canine kidney cell culture. Studies to date indicate that whichever cell culture medium is used, the reactogenicity and efficacy of a given vaccine strain is the same. For all practical purposes, the live virus measles vaccine may be considered free of penicillin, streptomycin, neomycin and polymyxin.

D. Clinical response to vaccination

The live vaccine produces immunity by inducing a mild or inapparent, non-communicable measles infection.

1. Fever and Rash

Most children experience some fever associated with the attenuated measles infection. The fever normally begins about the sixth day after vaccination and lasts for two to five days. Despite this, children are generally without symptoms, such as malaise and anorexia, unless the fever exceeds $103^{\circ}F$.

Approximately 20 to 40 percent of those given Edmonston B strain vaccine develop fever $\geq 103^{\circ} F$; a modified measles-like rash occurs in about half of the children vaccinated. This rash develops about the time of onset of fever or shortly thereafter. Among those given Schwarz strain vaccine, the frequency of febrile responses $\geq 103^{\circ} F$. is about half that

observed following Edmonston B vaccine; the duration of fever is somewhat shorter and the frequency of rash is reduced to 15-20 percent.

Several of the vaccine manufacturers have asserted that febrile reactions among children given "production lots" of vaccine (i.e., vaccine produced for commercial use) are much less frequent than were observed when "test lots" of vaccine (i.e., vaccine produced before licensure for evaluation purposes) were employed. The results of several companysponsored studies supporting this concept have been circulated. These manufacturers have proposed that the several additional tissue culture passages effected between "test lots" and "production lots" may have resulted in further attenuation of vaccine strains. Since the studies supsporting this hypothesis lacked certain elements of previously conducted independent, controlled trials, CDC conducted a double-blind placebocontrolled study in Honduras in 1965. Current production lots of Edmonston B strain vaccine (supplied by Merck, Sharp and Dohme) and Schwarz strain vaccine (supplied by Pitman-Moore) were evaluated. These studies showed that 26 percent of children given Edmonston B vaccine and 15 percent of those given Schwarz strain vaccine experienced temperatures ≥ 103°F. These results did not differ from those obtained by Krugman four years previously, at which time "test lots" of vaccine were used. Additionally, recent cooperative studies sponsored by WHO in Canada and Czechoslovakia revealed that marked febrile responses were still frequent occurrences (Cockburn, et al. Bull. WHO 34:223, 1966)

	% with Fe	ever ≥ 103°F.
	Edmonston B strain	Schwarz strain
Canada (Trial I)	58	15
Canada (Trial II)	59 vd madaya	21 21
Czechoslovakia	24	9

The differences observed in these various studies probably relate to the time and frequency with which temperatures were obtained.

In brief, there is no substantive evidence to indicate that "production lots" of either vaccine virus strain are "more attenuated" than the original "trial lots."

2. Other clinical findings

Koplik spots, pharyngeal hyperemia, cough, coryza and conjunctivitis have been noted to occur among vaccinees. The frequency of the latter three entities has not usually exceeded that observed among controls.

Occasionally, convulsions of the febrile type, occurring five to seven days after vaccination, have been recorded following administration of live measles vaccines. Not surprisingly, convulsions have been observed more frequently following administration of the Edmonston B strain vaccine which induces higher febrile responses with greater frequency than other vaccine strains. Illustrative control trials are shown below:

	Edmonston B strain		Schwarz	z strain	
menuface of order	No. of Children	No. with Convulsions	No. of Children	No. with Convulsions	
WHO trials $(1962/63)_{2}^{1}$	1201	25	108	1	
WHO trials (1964/65)2	183	3	372	1	
Honduras (1965) ³	93	1 7	91	0	

- 1. WHO Technical Report Series No. 263, Measles Vaccines, Geneva, 1963
- 2. Cockburn, et al. Bull. WHO 34:223, 1966.
- 3. Miller, et al. (CDC studies)

No sequelae have been observed in any of these children. Current use in the USA suggests that rates may be lower than those recorded here.

The WHO Scientific Group on Measles Vaccines also commented: "The convulsions occurred most frequently in infants and appear to have been a consequence of fever and not of specific involvement of the central nervous system by measles virus. The reports of convulsions were usually based on information supplied by parents and may not always have been accurate." It is to be noted also that some convulsive episodes may have been coincidentally rather than causally related to vaccine administration.

Because of these several considerations, calculation of specific rates for convulsive episodes by vaccine strain is not warranted. It would seem reasonable to conclude, however, that such episodes are more frequent following administration of a more reactogenic vaccine.

Measles vaccines may suppress tuberculin skin positivity for a period of weeks to months. Nevertheless, although exacerbations of tuberculosis have been noted following natural measles, none have been recorded following "vaccine measles".

Children suffering from a variety of disabling conditions, e.g. tuberculosis, asthma, malaria, cystic fibrosis, malnutrition, chronic pulmonary conditions, and congenital abnormalities of various types, have been given vaccine without adverse effect. It is possible that difficulties might be encountered, however, in children with malignancies. Of eight children with leukemia who were vaccinated in one study, one died from an apparently subchronic measles infection.

Careful studies of children highly allergic to eggs or egg products have revealed no allergic sensitivity problems consequent to administration of chick embryo cell culture vaccines.

A decline in platelet counts has been observed (NEJM 275:352, 1966) following administration of Edmonston B strain vaccine, beginning on the second day after vaccination and lasting for 10 to 14 days (maximum depression at day 3-7). This phenomenon was exhibited in 38 of 44 children studied; the mean reduction was 98,000/cu. mm. The cause is felt to be a decrease in platelet production. There have been no known adverse consequences resulting from this phenomenon. No studies have been recorded following administration of Schwarz strain vaccine.

E. Antibody response and protective efficacy

An antibody response occurs among more than 95 percent of those given any of the live virus measles vaccines described above. The height of the initial

antibody level achieved and the relative heights of the antibody levels maintained for at least four years appears to be directly correlated with the height of the initial febrile response. Thus, the Edmonston B strain vaccine induces the highest antibody levels initially and higher relative titers are maintained.

The implications of lower antibody titers with respect to actual protection against the natural disease among those given the Schwarz strain and other further attenuated virus vaccines have been a subject of scientific debate. Although no data have been presented to date to indicate that those receiving the further attenuated measles vaccine strains have actually experienced declining or decreased protection against natural measles, several have argued that this might occur. Since one side of this argument has been rather forcefully presented to African health officials during the past year, the various pertinent studies and observations bearing on this question are presented here in some detail.

1. Antibody response

Hemagglutination-inhibition (HI) antibodies which are induced following natural measles, the administration of Edmonston B vaccine and the administration of further attenuated (Schwarz) vaccine are shown in Figure 1. These figures are taken from the paper by Krugman, et al (J. Pediatrics 66:471, 1965) and are representative of results obtained by others. The HI determinations were obtained by the method described by Rosen (Virology 13:139, 1961). It is to be noted that mean antibody titers following natural measles or the administration of Edmonston B vaccine are higher than those following the administration of Schwarz strain vaccine. Further, a number of children given Schwarz strain vaccine had no detectable HI antibodies after two years.

It was noted, however, that the results of the HI tests performed by Rosen's method did not fully correlate with protection as measured under

circumstances of challenge by natural disease or with live virus vaccine. Recently, a more sensitive modification of the HI test devised by Norrby (Virology 19:147, 1963) has been used. It is reported to be five to ten times more sensitive in detecting measles antibody.

Shown below are recent results reported by Krugman (personal communication) which were obtained among institutionalized children who had not been exposed to natural measles virus after vaccination:

Serological Responses at 1 month and 4 years - HAI (Norrby)

	No. of	1 m	onth	4 years		
	Children	G.M.T.	* Range	G.M.T.*	Range	
Natural measles	46	362	(64-4096)	108	(8-2048)	
Edmon. B.	43	536	(36-4096)	115	(8-2048)	
Edmon. B.+G.G.	41	480	(64-4096)	75	(8-512)	
Schwarz	75	344	(16-1024)	28	(2-512)	

*Geometric mean titers

It is to be noted that mean antibody titers were lowest among those given Schwarz vaccine; however, antibody was detectable in all children.

2. Protection against natural disease

In field trials employing Edmonston B strain vaccine and Schwarz strain vaccine, a few cases of measles have occurred among vaccinated children.

This is in accord with the observation that, for obscure reasons, a small percentage of children (5 percent or less) fail to respond serologically after administration of fully potent vaccine. It is presumably those children who may experience measles when exposed.

There have been few studies to measure the duration of protection after measles vaccine administration. Since measles vaccine has only recently become available, the duration of observation is comparatively brief.

Edmonston B vaccine was not given to significant numbers until 1960 and Schwarz strain vaccine not until early in 1962.

Field trials of Edmonston B vaccine have now extended observations to five years; no decline in efficacy has been observed. A field trial involving 450 New York City children given Schwarz strain vaccine late in 1961 and early in 1962 shows no apparent decline in efficacy to date, i.e. over a four-year period (Krugman, personal communication). In this latter group, 35 percent, by history, have had known exposure but no cases have resulted.

An additional study providing some information regarding the efficacy of measles vaccine as employed in the field has been reported from Los Angeles (Wehrle, personal communication). In February, 1966, a question-naire was distributed to all members of the Los Angeles Pediatric Society asking that these physicians record the numbers of doses of vaccine administered and the number of clinical cases of measles they subsequently observed in the children vaccinated. The following represents the analysis of a 10 percent sample of the forms returned.

Vaccine	No. of Doses Given	No. of Vaccine "Failures"	Percent of Total
Edmonston B	3625	1	0.028
Edmonston B + G.G.	22485	6	0.022
Schwarz	10045	2	0.020

The Los Angeles study can be criticized from many standpoints; vaccine doses recorded were given over a period of years; the Edmonston B strain vaccine has been available longer than the Schwarz strain vaccine; there is no guarantee that the vaccinating physician would necessarily see a subsequent presumed case of measles; some children vaccinated were probably naturally immune to measles; almost certainly some cases of "clinical measles" were not measles at all. Despite these various deficiencies, it appears that vaccine failures to date are infrequent and, further, that no major differences have yet been manifested between the vaccines employed.

The only suggestion that Schwarz vaccide has failed to induce protection comes from Mali. In the 1966 report of the Division of Social-Preventive Medicine it is stated that "there have been cases of measles occurring in vaccinated persons in Bamako and in the interior of the country." It is noted in the report, however, that Schwarz strain vaccine was first used in January, 1966, and that measles outbreaks were already in progress when the vaccination teams reached the field. Since excellent protection with Schwarz strain vaccine over a period exceeding six months has been clearly shown in several studies, it would seem reasonable to assume that the problems in Mali might have resulted from vaccination during the incubation period of measles or from vaccination during the incubation period of measles or from difficulties with vaccine preservation. An effort to determine the cause is reported to be in progress.

3. Response to challenge of children with low antibody titers

Available data indicate that individuals with low measles antibody titers who are exposed to naturally occurring measles virus experience an increase in antibody titer without clinical symptoms.

Stokes, et al (Am. J. Hygiene 74:293, 1961) discovered that six children with low, naturally-acquired neutralizing antibody titers experienced, during the course of a measles outbreak in an institution, sharp increases in antibody titers without evident illness.

No suith / fold

Initial antibody Pre-epidemic	No. of Children	or greater in- crease in titer	Maximum titers
na sku 2°m Tillw somb	3	is reduced having a	32,32+
WHITE CLASS SECTION	11 3 4 7 11 11 11 11 11 11 11 11 11 11 11 11 1	Let salso 2 to exe	32,16
dust to the 8 carles	lyib6 and in	o mokishtigansa ini	128,64
verdi 16 deleven ol	alsi 4 feet fi	rist collection of decisions decisions	
32 0349869 3008	6	uns stato na tota.	
64	10	0	
128-256	2	0	

Krugman (J. Pediatrics 66:471, 1965) exposed to natural measles two children whose HI antibodies (Rosen method) had fallen to undetectable levels after vaccination with Schwarz strain vaccine. Both children experienced sharp increases in antibody titer following exposure but neither, under close observation, had symptoms.

		Meas1	es HI Antibody	Titer	s	
Child #1		Before vacc.	1 mo. after vacc.	1963	1964 pre- exposure	2 mos. after exposure
HI Titer	(Rosen method)	<8	32	<8	<8	256
HI Titer	(Norrby method)	<8	128	16	32	≥ 2048
Child #2						
HI Titer	(Rosen method)	< 8	256	<8	<8	128
HI Titer	(Norrby method)	<8	256	16	(ND)	≥2048

An explanation for the observation that marked increases in antibody titer may occur without illness is found in studies (Krugman, et al. J. Pediatrics 66:471, 1965) which demonstrated an accelerated antibody response in previously vaccinated children when they are revaccinated with live, attenuated strains. (Fig. 2)

4. Summary

Two hypotheses might be advanced with the data presently in hand:

- a. Decreased initial and less persistent antibody responses among those given further attenuated vaccines will result in significant numbers of vaccine failures within a comparatively few years.
- b. Initial sensitization of the individual to the measles virus antigens through vaccination will enable him to develop antibody more rapidly on later exposure and infection without symptoms.

Data to date favor the second hypothes s. Since measles is readily propagated in West Africa, as evidenced by high attack rates among very young children, and since the West African program was not conceived as a "measles eradication" program, there is every reason to expect that children with lower antibody levels will develop high levels of antibody without illness when naturally exposed.

F. Age at vaccination

Serologic studies and studies of age specific attack rates for measles in various parts of West Africa indicate that by the time children reach their fifth birthday, probably 90 percent or more have contracted the disease.

Immune by Serologic Sampling

Age	Cumulative %
6-12 mos.	5.9
1	13.5
2	42.5
3	66.6
4	84.4

(Hendrickse, et al. J. Trop. Med. and Hygiene 69:112, 1966)

Measles in 1000 Consecutive Outpatients

%	Cumulative %
34	34
38	72
16.4	88.4
4.6	93.0
	34 38 16.4

(Morley, Am. J. Dis. of Children 103:230, 1962)

The proportion immune as portrayed by Hendrickse may be somewhat lower than they are in fact since, as he has pointed out, his method for antibody detection is comparatively less sensitive than those employed by others.

The upper limits for vaccination against measles might thus logically be established at three or, at the most, four years of age. A small percentage

of susceptibles would not be vaccinated with this age limitation. However, case-fatality rates are substantially lower among older children than among those at the so-called "weanling" period.

Vaccination of children younger than about six months of age is of no value since these children sill have sufficient maternal antibody to prevent growth of the virus and thereby development of the attenuated measles illness which induces immunity. The proportion who are resistent by virtue of circulating maternal antibody falls rapidly about the sixth month of life. However, a small percentage will continue to be resistent to infection through about the ninth month.

Susceptibility to Live Measles Virus Vaccine by Age in Months (from various studies)

I. Edmonston B Strain Vaccine

	Age in Months							
	2	3	4	5	6	7	8	9-11
No. of Children	1	1	23	23	69	62	49	159
No. with Seroconversion	0	0	4	7	39	49	48	155
Percent Conversion	01 51	10	17	30	57	79	98	97
II. Schwarz Strain Vaccine			4	5	6	7	8	9-11
No. of Children			1	3	34	13	12	105
No. with Seroconversion			1	2	21	11	12	101
Percent Conversion			100	_	62	84	100	96

G. Vaccination during an epidemic

Among a number of West African health officials, there is concern about administering measles vaccine during an epidemic. Some have expressed fear that the vaccine illness and the natural illness might be additive in severity. There is no basis for this concern.

Studies have shown that if measles vaccine is administered at the time of exposure or within a day or two thereafter, the vaccine-induced infection, with a shorter incubation period, will block the natural disease. If administered later than this, the natural disease will prevail. Never, however, is an additive effect seen.

It must be recognized, however, that the population concerned may not be able to understand that measles vaccine administered to an apparently well child late in the incubation period will not prevent the natural disease.

Severe cases of measles occurring soon after vaccination may therefore be attributed to the vaccine itself.

In the USA, measles vaccine is now used to control epidemics, i.e., vaccine is administered in the face of a developing epidemic. However, education of the population as to what the vaccine can and cannot do is a great deal simpler in the USA than in Africa.

H. Administration of measles vaccines simultaneously with other live virus vaccines

Smallpox, measles and yellow fever vaccines are all live, attenuated viruses and produce infection in the vaccinee. Concern has been expressed regarding the safety and efficacy of administering two or more of these agents simultaneously. Both smallpox and yellow fever (especially the Dakar strain) vaccines are known to cause central nervous system complications in a small proportion; natural measles results in encephalitis in approximately one per thousand afflicted.

Only limited studies have been carried out to determine the safety and efficacy of simultaneous inoculation of these agents.

% Temp. ≥103°F.*

Author	Edmon.B Spox - YF	Edmon.B Spox	Becken- ham-Spox	Edmon.B.	Spox Y	-Fever
Meyer ¹	20(6)	23(2)		20(4)	11(1)	12(4)
Togo ² (CDC)		39(24)		30(6)	19(10)	
Hendrickse ³		29	10		9	
Weibel ⁴		28			0	

- * Approximately 100 children were tested in each vaccine group with the exception of the fourth study (see footnote).
- Meyer, et al. Bull. WHO 30:783, 1964
 Studies were carried out in Upper Volta; vaccines were mixed for purposes of administration; proportion with high temperatures recorded in table are shown for ≥39.0°C. (102.2°F.) and, in parentheses, for temperatures ≥40°C. (104°F.)
- 2. Budd, et al. (CDC studies) Vaccines were administered simultaneously but in opposite arms.
- 3. Hendrickse (personal communication)

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- 4. Weibel, et al (Pediatrics 37:913, 1966)
 Studies were conducted in Pennsylvania; vaccines were mixed and administered; two studies were done in the same population group; children were apparently studied in an identical manner. In one group 5 of 12 developed fever ≥103°F.; in the other group 0 of 6.

The Meyer study demonstrated no differences in the frequency of febrile responses among those given measles, measles/smallpox, and measles/smallpox/ yellow fever vaccines. The proportion showing significant febrile responses is, however, remarkably low contrasted to most other studies of Edmonston B vaccine. No explanation is apparent.

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In Hendrickse's study and in the CDC-Togo study, the febrile responses following administration of measles and smallpox vaccines were notably greater than when measles vaccine or smallpox vaccine was given alone.

In terms of serological efficacy, responses throughout appeared to be identical whether a vaccine was given alone or in combination with others with one exception only. Yellow fever vaccine given as a mixture in the same site with smallpox vaccine resulted in Y-F serological responses in 85 percent as opposed to > 95 percent when yellow fever vaccine was administered by itself. Studies by Meers (Trans. Roy. Soc. of Trop. Med. and Hyg. 54:493, 1960) clearly document decreased efficacy, down to about 80 percent, when yellow fever vaccine is mixed with smallpox vaccine for administration by scarification.

During 1965, CDC and Panamanian Health Authorities evaluated 5261 children to whom measles (Edmonston B) and smallpox vaccines were simultaneously administered (CDC unpublished data). Of the 5261, 4250 were estimated to be non-immune to both measles and smallpox. Complications which occurred during the 14-day post-vaccination period included 11 convulsive episodes, 6 cases of generalized vaccinia and 11 cases of autoinoculation vaccinia. One death occurred in a 5-year old girl who had bronchitis before vaccination and subsequently developed fever and diarrhea, and died on the eighth post-vaccination day. It was felt that the death was unrelated to vaccination but incomplete documentation precluded a definite conclusion.

In 1965-66, combined measles/smallpox vaccine was given to 18,000 children in Upper Volta in a study sponsored by that government and the Merck Institute (Kalabus, et al, personal communication). The vaccine was given by jet gun; 0.5 ml. was injected with the gun at a short distance from the skin surface so that some vaccine was deposited intradermally. It was reported that "the vaccine elicited a primary, vaccinoid or immune take reaction in 98 percent" (conventional WHO designations are not given). There was no indication of interference between the vaccines as measured by antibody or dermal response.

The investigators also state: "there was no evidence for serious reaction or for increase in clinical reactions above that expected for either vaccine given alone."

Summary regarding multiple vaccine administration

Other than the Meyer study and the last cited study from Upper Volta (the evaluation of which requires further documentation), it would appear that the simultaneous administration of two or more of three live-virus vaccines (small-pox, measles, yellow fever) results in a more pronounced febrile response, etc. than does the administration of a single agent. Although the simultaneous administration of smallpox and measles vaccines has been tested in reasonably large numbers of susceptibles, only 100 children (Meyer study) have been evaluated with respect to simultaneous administration of all three agents.

Given at separate sites, there does not appear to be a decrease in the serological efficacy of any of the components. When given as a mixture, however, there may be a decrease in the efficacy of the yellow fever component.

At this time, it seems reasonable to proceed with simultaneous administration of measles and smallpox vaccines. Continuing field observations, however, are indicated. Yellow fever vaccine should not be added to this battery before careful field trials have demonstrated that it results in effective immunization.

The practical advantage of a measles/smallpox vaccine mixture or possibly even a measles/smallpox/yellow fever vaccine mixture has been suggested. In the present program, there would appear to be little advantage to this. At present, one gun is required to administer smallpox vaccine to persons of all ages and one gun to administer measles vaccine to young children. The availability of a measles/smallpox vaccine mixture would eliminate the need for one injection in young children; the saving in time would be comparatively small and would probably not (on the basis of past experience) compensate for the increment cost of a vaccine mixture; two guns would still be required as before.

I. Vaccine Stability

Live measles virus vaccine is much more sensitive to heat and to light than smallpox vaccine.

Precise measurements with regard to stability at different temperatures and for different times are limited in number. To provide some estimates regarding the limitations of time and temperature, we have taken data from studies conducted at CDC and by the manufacturer and endeavored to construct curves by time for different temperatures for the vaccine both in its desiccated form and in its reconstituted form (Figures 3 and 4). In arriving at estimates of stability, we have been conservative, weighting the results, in general, toward the side of the less favorable results. Although results of testing with Schwarz strain vaccines were used for the determinations, data submitted by the manufacturers suggest that the stability of the Edmonston B strain vaccines is not significantly different.

1. Desiccated vaccine

The keeping properties of the vaccine (Schwarz strain) are excellent at 39°F. (4°C.) and quite good for at least 7 days at 71°F. (22°C.).

However, as shown in the figure, potency drops rapidly when vaccine is kept above this temperature. Temperature and absolute maximum keeping time in the field are as follows:

Temperature	Max. Time (Days
86°F.	3
97°F.	2
104°F.	2

If kept at higher temperatures for this extended period, the vaccine would have to be used very promptly after reconstitution for, as shown below, once reconstituted, the vaccine rapidly loses potency.

2. Reconstituted vaccine

When used at cooler temperatures, 71°F. (22°C.) or less, the vaccine (Schwarz strain) remains reasonably potent for at least 24 hours. However,

within two hours after reconstitution at 99°F. (37°C.), vaccine potency declines by at least one log in titer and probably is impotent after two hours.

From these figures, various estimates of time and temperature relationships can be made to work out operational logistics. For example, if we assume that the vaccine, when it arrives in the country, has potency of 3.4 logs (tissue culture infective doses) and loses 0.5 logs in titer during transport to the field, it may be assumed that it will become ineffective within about one hour after reconstitution and use at 99°F. (37°C.)

3. Effect of light

The vaccine is not only highly sensitive to heat but may be even more rapidly inactivated by exposure to light. Vaccine titers decline much more slowly in amber bottles; additionally, a protective shield, as provided by the label serves as a further, valuable barrier to sunlight.

4. Disposal of vaccine at end of day

If reasonable precaution has been taken with the refrigeration of vaccine and the last vial of reconstituted vaccine has not been in use for more than an hour at a temperature of $100^{\rm O}$ F. or less, it would seem reasonable to retain the remaining portion of vaccine in the vial overnight, under refrigeration, for immediate use the following morning. Unused portions of vaccine vials should not be kept unless these minimum conditions can be met.

PATTERN OF HEMAGGLUTINATION-INHIBITION (HI) ANTIBODY RESPONSE
FOLLOWING INITIAL VACCINATION AND SUBSEQUENT REVACCINATION
OF CHILDREN WHOSE ANTIBODY TITERS HAD FALLEN TO NON-DETECTABLE LEVELS

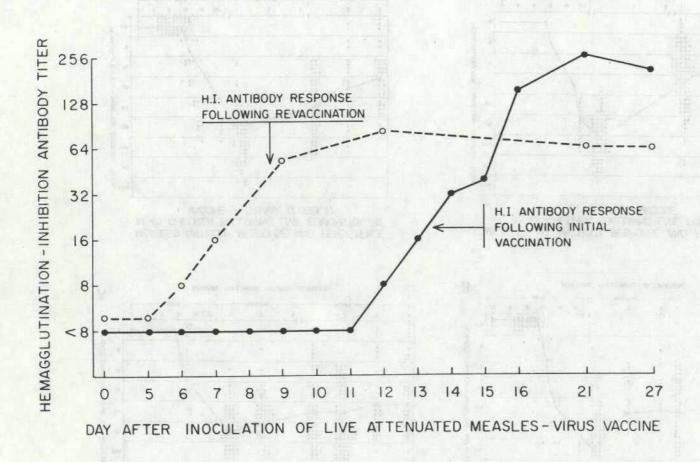


Figure 2. Comparison of the pattern of HI antibody response following initial vaccination with live attenuated measles-virus vaccine (solid line), and subsequent revaccination of children whose antibody titers had declined to non-detectable levels (interrupted line). Following the initial vaccination, antibody was detected first on the 12th day and peak levels were observed on the 21st day. Following the revaccination, antibody appeared earlier, on the 6th day, and peak levels were reached by the 12th day. Assay for HI antibody was performed by method of Rosen 11.

(From Krugman)

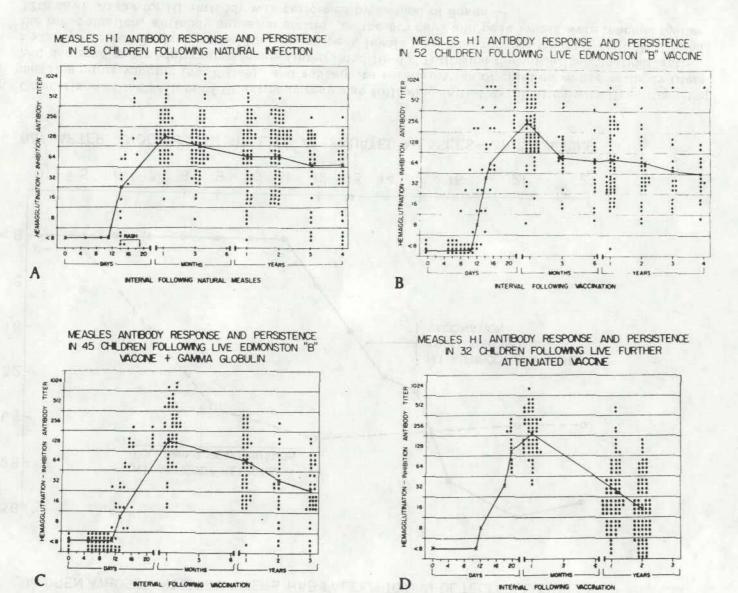


Figure 1. The pattern and persistence of the HI antibody response following -A. natural infection, B. live attenuated measles-virus vaccine, Edmonston B type, C. live Edmonston B vaccine plus gamma globulin, and D. live further attenuated measles vaccine. Each black dot represents one of the serial HI antibody determinations performed by the method of Rosen 11. Solid line indicates the geometric mean antibody titer.

(From Krugman)

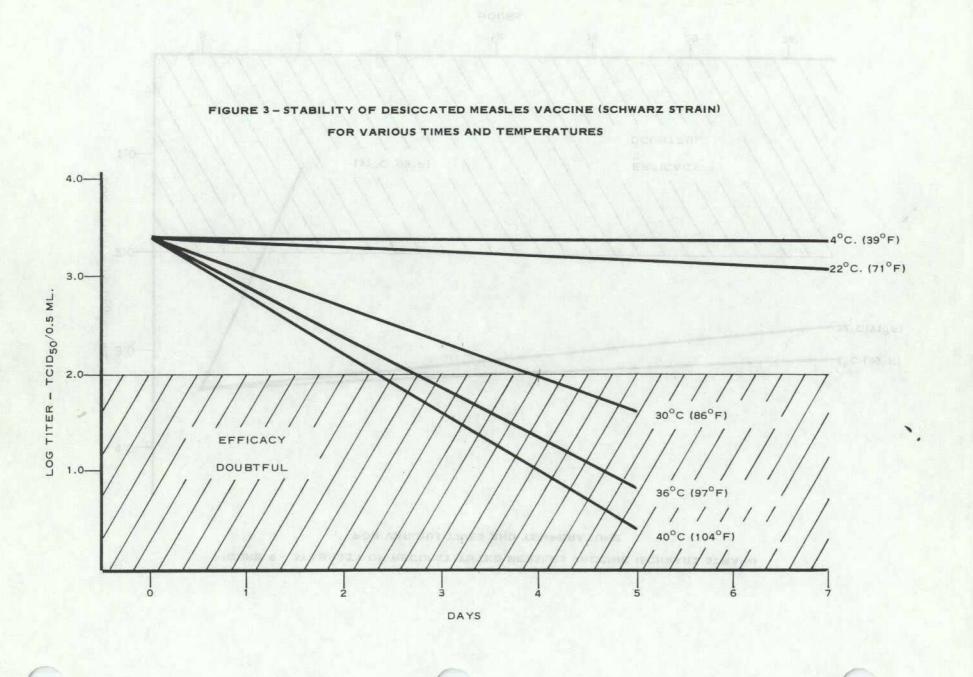


FIGURE 4 - STABILITY OF RECONSTITUTED MEASLES VACCINE (SCHWARZ STRAIN) FOR VARIOUS TIMES AND TEMPERATURE 4.0-LOG TITER - TCID50/0.5 ML. -4°C (39°F) -22°C(71°F) (37°C 99°F) EFFICACY 1.0-DOUBTFUL 24 12 HOURS

TECHNICAL CONSIDERATIONS

II. SMALLPOX VACCINE AND VACCINATION

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TECHNICAL CONSIDERATIONS

II. SMALLPOX VACCINE AND VACCINATION

A. Introduction

This section on smallpox vaccine and vaccination provides information of practical use for the West African Smallpox Eradication and Measles Control Program. Subjects covered include smallpox vaccines, clinical response to vaccination, serological response to vaccination, the efficacy of smallpox vaccination in protection against smallpox, techniques and mechanics of vaccination, indications and contraindications for smallpox vaccination, and the simultaneous administration of smallpox vaccine with other immunizing agents.

B. Smallpox Vaccine

1. General

Smallpox vaccine consists of infectious vaccinia virus particles. It is distributed both in a freeze-dried (lyophilized) form and dispersed in a glycerine or lanolin medium. It is dispensed in a concentration adequate to infect non-immune and partially immune persons by cutaneous inoculation. The effectiveness of the vaccine is determined by the concentration of live infectious virus particle at the moment of its application to the skin, not by its virus content at the time of production. It is imperative that handling in storage, shipment and application be such that adequate potency is preserved.

2. Vaccine Virus (Vaccinia) Strains

Many different strains of vaccinia virus are used for the preparation of smallpox vaccine. The origins of few, if any, are known. It is highly improbable, however, that any of them were derived directly from variola virus (Herrlich, A., et al: Arch. Virusforsch. 12:579, 1963). There is no evidence that strains producing severe local reactions and marked

systemic disturbances confer better protection than strains producing milder clinical reactions. Therefore, strains of lesser pathogenicity are preferred for vaccine production.

Most vaccines produced in the United States, including those that will be used in West Africa, are derived from the New York City Board of Health strain. The origin of this strain is not precisely known, but it presumably came to the U.S.A. from England in the 1800's. The human pathogenicity of this strain has not been directly compared with European or other vaccinia strains but observation of clinical reactions following vaccination in various parts of the world indicate that the present United States vaccines compare favorably with those generally considered to be least pathogenic (Elstree Strain, England).

C. Vaccine Production

1. Systems Employed

a. Animals

Most smallpox vaccines are prepared from virus grown on the skin of young animals (cow calves, water buffalo calves, lambs, etc.).

Young animals are preferred as they are less likely than older animals to be infected with tuberculosis.

At present, vaccines derived from animal sources are usually preferred because of the extensive, satisfactory field experience with these vaccines and the fact that they generally are more stable than vaccines derived from other systems.

Bacterial contamination cannot be avoided in vaccines derived from animal culture. Such contamination is minimized by scrupulous care and cleanliness in preparation of the skin areas vaccinated, and of animal quarters. The "harvest" is processed to reduce bacterial contamination to a minimum while retaining maximum virus potency. Antibacterial substances used to reduce bacterial counts

are phenol, neoymycin, polymyxin, and streptomycin. The antibiotics employed are only those known to have no, or little, tendency to induce sensitization. The antibiotic concentration which remains after processing is very small. Sulfonamides and penicillins are not used as antibacterial agents because of their potential for inducing hypersensitivity reactions in susceptible individuals. Even with present antibacterial techniques, it is extremely difficult to produce vaccine lots which are consistently bacteriologically sterile. However, vaccine lots containing 0 to 5 non-pathogenic organisms per ml. of packaged vaccine can be achieved with consistency. Extensive and thorough testing for pathogenic and anaerobic organisms is done on each lot. All lots found to contain such organisms are discarded.

b. Chicken Egg Embryonic Membranes

Vaccines prepared from the chickembryo chorio-allantoic membrane

(CAM) are currently being produced for general use in Sweden, Brazil
and, in limited quantities, in the United States. Vaccines prepared
on the CAM are frequently found to be bacteriologically sterile. Egg
vaccines when freeze-dried have not yet been shown to be as thermostable
as freeze-dried vaccines of animal origin. For production purposes, it
is recommended that CAM vaccines be passaged not more than five times
as it is known that high egg passage vaccinia virus may be reduced
with respect to immunogenicity. To date, chicken egg CAM derived
vaccines have not been extensively used in smallpox endemic areas to
compare their effectiveness to vaccines prepared from animals. On
theoretical grounds, it is probable that potent low passage egg
vaccine prepared from animal passage seed virus will prove to be as
effective as the animal grown material.

An additional problem in the production of vaccines in the chick embryo is that they must be produced in eggs from flocks

known to be free from disease, including avian Leucosis virus and other potential oncongenic viruses, i.e. Rous virus.

c. Tissue Culture

The production of smallpox vaccines in tissue culture in the experimental stage. Such a method would logistically simplify production and should make possible the production of consistently sterile vaccine. However, successful large-scale production of a vaccine known to contain no adventitious viruses has not been attained. Even when this is achieved, traditional methods should not be abandoned until tissue culture vaccines can be shown to be as safe and effective as the best traditional vaccines.

D. Vaccine Stability

1. General

All smallpox vaccines deteriorate in potency when stored above freezing temperatures; however, freeze-dried vaccines are vastly more heat stable and retain potency longer than liquid or lanolinated vaccines.

The data on stability indicate considerable variability among the smallpox vaccines produced by various manufacturers throughout the world. Specific statements on stability will be limited to U.S.-produced vaccines. These data will in general apply to all vaccines meeting the Requirements for Smallpox Vaccine (Annex No. 5) as set forth in the WHO Technical Report Series No. 323 (1966) as revised in 1965 by the WHO Expert Committee on Requirements for Biological Substances. The WHO Expert Committee recommends that the expiry date for liquid vaccine should not be more than three months, and for freeze-dried vaccine not more than 12 months from the date on which vaccine was issued by the manufacturer or from a storage depot. As will be pointed out, these recommended expiry dates are highly conservative.

2. Liquid and Lanolinated Vaccines

Liquid smallpox vaccine deteriorates rapidly at even moderately high temperatures and after exposure to direct sunlight.

- a. Liquid vaccines stored at freezing temperatures (lower than 0° C. or 32° F.) can be assumed to retain full potency for only three months after release from the manufacturer.
- b. Liquid vaccine stored at the usual refrigerator temperatures (0°C. to 10°C. or 32°F. to 50°F.) can be assumed to retain full potency for no more than <u>seven days</u> after removal from sub-freezing storage conditions. Liquid vaccine stored at higher temperatures should be discarded after 24 hours.

Lanolinated vaccines have been popular in West Africa because of their presumed superior heat stability over liquid vaccines. It is doubtful, however, that the heat stability of lanolinated vaccine is any better than the glycerinated vaccine. L. H. Collier (J. of Hygiene 53:76, 1955) has shown marked deterioration of both glycerinated liquid lymph and lanolinated lymph vaccines after storage at 37°C. (99°F.) for one week. Preservation was not greatly improved when the holding temperature was reduced to 22°C. (73°F.).

3. Freeze-dried (Lyophilzed) Vaccine

a. General

Freeze-dried vaccine has been shown to be remarkably heat stable. Briefly, freeze-dried vaccine consists of a suspension of vaccinia virus partially purified by differential centrifugation and by exposure to phenol and antibiotics in a solution of peptone which acts as a stabilizing agent. The suspension is dried in a centrifugal freeze-drier (lyophilizer) to remove all but traces of moisture and sealed in vials under vacuum.

In addition to the improved thermostability, the freeze-dried vaccine is of much greater purity than ordinary vaccine lymph; it is virtually free from contaminating bacteria and tissue debris of the host animal. Consequently, it is possible that freeze-dried vaccine may produce less local secondary reactions than ordinary liquid vaccines although this has not been documented.

b. Heat Stability of Freeze-dried Vaccines

Despite the fact that freeze-dried smallpox vaccine is highly heat resistant, this thermostability is a relative property. Hence, it is desirable that it be stored at the coldest possible temperatures at all times. Ideally, vaccine should be stored at sub-freezing temperature; however, with large stores of vaccine, this is rarely practicable even in the United States. A second choice for vaccine storage is at temperatures ranging from 0°C. to 10°C. (32°F. to 50°F.) This form of storage should be readily available in Africa, in capital cities and other centers where supplies can be stored for regional distribtuion. Refrigeration facilities need not necessarily be associated with medical installations. If necessary, use can be made of available commercial refrigeration such as might be found in local abattoirs, etc. Freeze-dried vaccine stored at temperatures under +10°C. can be expected to maintain full potency for at least two years. When refrigeration is not available, the coolest available location, such as thick-walled storehouses or similar structures, should be utilized. Vaccine should never be allowed to stand in direct sunlight even when in shipping cartons.

The following table indicates the stability of freeze-dried smallpox vaccine manufactured in the United States:

(1) Unreconstituted Vaccine

Storage Conditions
Interval with Full Retention of Potency
Constant 25°C. (77°F.)

18 months

Constant 37°C. (99°F.)

at least 3 months*

* Testing at 37° C. has been done only to the three-month interval at this time. Further testing to extend the period of observation at 37° C. is currently in progress.

There is reason to believe that thermostability of U.S. vaccines at 37°C. will extend considerably beyond the three-month interval.

R. M. Cross, et al (Lancet, March 2, 1957, pp. 446-448) have presented data on freeze-dried vaccine produced at the Lister Institute in England which indicate that full potency can be retained for two years at storage temperatures of 37°C. and 45°C.

Storage Where Temp. Time. Titrated*	Titer on Chorio- allantoic Membrane (Infectious Units/ ml.)	No. of Men Vaccinated	% Vaccination* Success Rate (Scratch Technic
(64 wks. A	2.5 x 10 ⁸	100	100
64 wks. A 37°C. 106 wks. A	3.8 x 10 ⁸	- 88	100
В	1.8 x 10 ⁸		
(64 wks. A	1.1 x 10 ⁸	100	100
64 wks. A 45°C. 106 wks. A	3.4×10^{7}		
В	1.8 x 10 ⁸	87	100

^{*} A - Lister Institute, London, England B - University of Liverpool, England

After two years (106 weeks), there was still no detectable decrease in the pock count of samples stored at 37°C., although there was some decrease in potency as measured by rabbit scarification (data not shown).

The samples stored at 45°C. showed a slight decrease in pock count measured in one laboratory, but not the other. The samples stored at

^{**}No mention is made as to whether these rates represent primary vaccination or revaccination responses although at the virus titers recorded, vaccine potency was sufficient to have produced excellent take rates in either primary vaccinees or revaccinees.

both temperatures still produced 100 percent successful vaccinations. There was no evidence of any modification of the vesicular lesions obtained and no difference between the reactions produced by the samples stored at the higher temperatures and by those kept at -10° C.

It is presumed that American vaccine will follow a similar stability curve for at least 12 months. There is, however, one difference in the packaging of the English and American vaccines which does not permit a broader generalization. The English vaccine is packaged in flame-sealed glass vials which are essentially airtight. U.S. vaccines are packaged in bottles with rubber stoppers which are tightly secured by aluminum bands crimped in place. This stoppering is thought to be airtight, but has not been tested for complete air and moisture exclusion at intervals of one and two years. The high humidity encountered in West Africa may shorten shelf life at ambient temperatures if the seal is not complete. This is yet another reason why unreconstituted vaccine should be stored at refrigerator temperatures whenever possible.

A practical method for assessing vaccine stability in the field is by determining the vaccination "take rate" or "success rate" in primary vaccinees and revaccinees.

Freeze-dried vaccine produced in the United States has a virus titer of approximately $10^{8.3}$ TCID $_{50/ml}$. (Tissue Culture Infectious Doses $_{50/ml}$.) or the approximate equivalent of this in pock-forming units (PFU) when measured on the Chorio-allantoic membrane of embryonated hen eggs $(10^{8.3}$ PFU/ml.).

For primary vaccination by traditional methods of vaccination

(multiple pressure or scratch technique), it has been shown that with

freeze-dried vaccine a take rate of near 100 percent (>98 percent) can

be achieved with a vaccine titer as 10^{W} as $10^{7.2}$ TCID $_{50/\text{ml}}$. With a titer of 10^6 TCID $_{50/\text{ml}}$, the take rate drops to about 50 percent. (W. C. Cockburn, et al, Bull. WHO $\underline{16}$:63, 1957; A. Espmark, Acta Path. et Microbiol. Scandinav. $\underline{63}$:97, 1965.)

For revaccination by traditional vaccination methods, a higher minimum titer is required to achieve 100 percent take rates (major reactions). This is to be expected as pre-existing immunity of varying degree must be overcome before vaccinia virus multiplication takes place with subsequent boost in immunity. A vaccine titer greater than $10^{7.5}~\rm TCID_{50/ml}$, is necessary to produce a 95 percent take rate in persons vaccinated at least 10 years previously. (A. Espmark as quoted above).

With intradermal jet vaccination, titers of 10^{6.3} TCID_{50/ml}. and 10^{7.0} TCID_{50/ml}. will induce take rates of 100 percent and 95 percent in primary vaccinees and late revaccinees respectively (Millar, J.D. and Roberto, R.R., Bol. Oficina Sanitaria Panamericana 57:537, 1964). When vaccination take rates fall much below 98 percent for primary vaccination and 95 percent for revaccination in those vaccinated 10 or more years in the past, vaccine potency must be questioned (assuming optimal technique has been employed).

In testing for suspected decrease in vaccine potency, two approaches can be utilized. The most direct method is to take representative samples from respective lots for titration in the laboratory. To insure that further decrease in virus titer does not occur during shipment, such specimens should be refrigerated. It is hoped that such titrations can be done at the Yaba Laboratory in Nigeria. If this is not possible, they can be done in Atlanta.

The second method can be accomplished in the field by comparing clinical "take" rates following use of the vaccine in question with those following a vaccine known to be potent.

If unreconstituted vaccine should go unused beyond the stated expiry date, do not discard it, but send samples to the laboratory for titration studies.

(2) Reconstituted Vaccine

(a) Freeze-dried Vaccine Used for Multiple Pressure or Scratch Method Vaccination

1. Under Refrigeration at 0-4°C. (32-39°F.)

The diluent for vaccine intended for vaccination by traditional methods contains 50 percent glycerin in sterile water. Glycerin is a vaccinia virus stabilizer. If maintained at normal refrigerator temperatures $(0-4^{\circ}\text{C.})$, American vaccine for multiple pressure or scratch use will maintain potency for three months. Vaccine remaining at the end of this time should be discarded.

2. No Refrigeration

In certain field situations (i.e. vaccinators traveling on bicycles to small outlying villages), refrigeration may not be available. Unused vaccine reconstituted during the day should be discarded to insure that potent vaccine will be used at all times. A large margin of safety exists with this recommendation. Reconstituted vaccine maintained at 35° C. (95°F.) for 4 days loses approximately 0.6 logs of titer (i.e. 10^{8} $-10^{0.6}$ = $10^{7.4}$) which should still give satisfactory take rates for both primary vaccination and revaccination.

(b) Freeze-Dried Vaccine for Jet Injector Use

Jet injector vaccine is the same as that used for multiple pressure or scratch vaccination; however, the diluent is different. The diluent for jet injector vaccine will be either 0.85 percent

sodium chloride (saline) or distilled water, neither of which contains glycerine. The jet injector vaccine diluent does not contain glycerine because the added viscosity of the glycerine tends to clog the vaccine delivery system. Without the stabilizing effect of glycerine on vaccinia virus, thermostability of reconstituted jet injector-vaccine is decreased.

Reconstituted vaccine for jet injection preferably should be used only on the day of reconstitution. However, if the residua in the final bottle or bottles used during a day can be refrigerated overnight, they may be used the following day without difficulty. At 37°C. (99°F.) reconstituted vaccine for jet injection does not significantly decrease in titer for three days. In emergency situations when a team may have run low on vaccine, it would be permissible to use reconstituted vaccine maintained at ambient temperatures on the second day after reconstitution. It is stressed that this should not be done routinely, but only under extraordinary circumstances.

Reconstituted vaccine should be protected from direct sunlight at all times to prevent virus inactivation. Whenever possible, vaccinations should be administered in a shaded area. Jet injector vaccine vials will be shielded by large labels to block sunlight penetration.

E. Smallpox Vaccination Methods in West Africa

1. The Mechanics of Vaccination

Several methods of vaccination will be employed in West Africa. The great majority of vaccinations will be given intradermally by jet injection. Traditional methods such as multiple pressure and linear scratch techniques will also be utilized in fixed installations and by members of mobile teams operating in remote, sparsely populated areas. The amount of vaccination

done by traditional methods will vary from country to country but in most countries this will not amount to more than 5 percent-10 percent of total vaccinations. All methods are based upon the placement of potent infectious vaccinia virus in target cells of the skin which lie in the basal layers of the epidermis. Vaccine virus deposited in subcutaneous tissue has little if any capacity to infect. When proper placement is accomplished, a limited, mild infection with vaccinia virus is achieved which induces immunity to smallpox for limited and varying degrees of time. The immunity engendered is not lifelong unless maintained by revaccination at regular intervals.

a. Site for Vaccination

The preferred site for vaccination (primary and revaccination) is on the outer aspect of the upper arm, over the insertion of the deltoid muscle, or slightly behind the midline of the arm. For jet vaccination, the area behind the midline presents a better site as it is more fleshy. The deltoid site offers several advantages. It is easily accessible, a most important consideration in mass campaigns. It is also an area which is not likely to be traumatized. In most tropical areas, it will be exposed to air, reducing chances for maceration from body moisture and secondary bacterial infection, particularly anaerobic infection with tetanus bacillus. Social customs and dress habits may introduce difficulty in using the deltoid area; in such cases an alternate site must be found. One such site is the flexor aspect of the lower arm. This site is definitely a second choice.

b. Preparation of the Vaccination Site

If the arm is visibly clean, the best skin preparation is none at all. When an arm is obviously dirty, i.e. caked with mud, it should, of course, be cleansed. Cleansing may be done with whatever agent is available. Water alone is preferred; soap and water is a second choice. Chemical agents should be avoided as they may inactivate vaccinia virus.

The cleansing procedure must be gently done so as not to produce minute abrasions of the skin, which may allow the development of secondary satellite vaccination lesions covering a large skin area.

c. Vaccination Techniques

The two techniques in general use are the multiple pressure and linear scratch methods. The predominant method employed in West Africa is the linear scratch technique. The instrument employed is usually a straight one-piece metal rod with a triangular-shaped blade at one end for making the scratch and a spoon-like arrangement at the other end which is dipped into the vaccine vial and used to smear vaccine into the scratch. In theory, the instrument is sterilized between each vaccination but often this is inadequately done. The number of insertions may be single or multiple, depending upon traditional practice.

For technical and scientific reasons, it is hoped that the multiple pressure method may eventually be accepted as the preferred technique. However, it should be recognized that it is difficult to alter traditional, devoutly-held medical practices despite rational arguments for change.

Comparison of results obtained by these two methods have been made by several workers (Parish, H.J., Brit. Med. J. 2:781, 1944; Mole, R.H., Lancet 252:597, 1947; Espmark, A., Quoted in J.A.M.A. 168:1801, 1958; and Bourke, G.J., et al, Brit. Med. J. 2:281, 1963). For primary vaccination, all have reported good results with take rates approaching 100 percent. With revaccination, the multiple pressure technique gives a slightly, though consistently, higher take rate.

With both techniques, success of vaccination is definitely related to the skill of the vaccinator. Cross (Cross, R.M., Bull. WHO <u>25</u>:7, 1961) reported a study in which 190 previously vaccinated subjects were simultaneously vaccinated by the scratch method on both arms of the same

individual by two different vaccinators. One elicited 92 percent major reactions, while the other elicited 62 percent major reactions. Benenson (Benenson, A.S., Arch. Environmental Health 7:96, 1963) reported an analogous observation with multiple pressure technique. It is anticipated that in situations where traditional vaccination is employed, such as infant clinics and remote villages, most persons will be primary vaccinees; good results can be obtained with either method.

The non-jet injector vaccine supplied for the program is packaged for multiple pressure use; however, it can be adapted for scratch technique without serious difficulty.

Comparison of Multiple Pressure and Linear Scratch Method of Vaccination in Young Adults*

A. Multiple Pressure Technique: Influence of Interval Since Last Vaccination

			Revaccination: Period in Years Since Last Vaccination				
Vaccination Reaction**		Primary Vaccination	0 - 4	5 - 9	10-14	15-19	20+
Successful	No.	105 97.2	27 69.0	40 69.0	30 90.9	65 81.3	169 88.5
Unsuccessful	No.	3 2.8	12 30.8	18 31.0	3 9.1	15 18.7	22 11.5
Total		108	39	58	33	80	191

B. Linear Scratch Technique: Influence of Interval Since Last Vaccination

	Reaction**		Revaccination: Period in Years Since Last Vaccination				
Vaccination 1		Primary Vaccination	0 - 4	5 - 9	10-14	15-19	20+
Successful	No.	99 97.0	22 59.0	32 50.8	14 58.3	67 76.1	138 80.7
Unsuccessful	No.	3 3.0	15 40.5	31 49.2	10 41.7	21 23.9	33 19.3
Total		108	39	58	33	80	191

^{*} Liquid calf lymph vaccine (Connaught Laboratories) stored at 7° C. was used. No mention of the vaccine virus infectious titer is made.

(Adapted from Bourke, G.J., and Clark, N. Brit. Med. J. 2:281, 1963).

^{**} Vaccinations were inspected on the 8th day. For a revaccination take to be recorded as successful the minimal lesion acceptable was a palpable indurated papule. Evidence of a central lesion (vesicle, pustule, central necrotic area or scab) was not required.

(1) Multiple Pressure Method

Initially, multiple pressure vaccine will be supplied in 100dose packages. Within the next year a 25-dose package will become available. A new type of applicator, the bifurcated needle
or "Dipstyck", is used to make the pressures. After diluent is
added to the freeze-dried vaccine to produce a homogeneous
suspension, the aluminum retaining seal and rubber stopper are
removed from the vial and replaced by a sterile plastic cap.
When vaccinations are to be performed, the cap is removed and the
"dipstyck" needle is inserted to the base of vial so that the
needle picks up a drop of vaccine in the space between the two
points of the needle. Multiple pressure vaccination is performed
in the usual manner.

The number of pressures recommended by the WHO Expert Committee on Smallpox for use with the traditional single-pointed needle are 10 for primary vaccination and 30 for revaccination. Use of the bifurcated, or two-pronged needle, reduces the number of pressures required for each by a factor of two if the needle points are both applied parallel to the skin. As vaccinators will not readily be able to differentiate between primary vaccinees and revaccinees when they come through the vaccinating line, it is suggested that a standard number of pressures be applied for both primary vaccinees and revaccinees (15 needle strokes, which equal 30 pressures). This will insure maximum take rates for both primary vaccinees and revaccinees. Since a small amount of vaccine is used, there is no need to wipe the site after vaccination with this method. When this technique is properly performed, no signs of bleeding will occur. A small amount of bleeding, however, does not interfere with establishment of vaccinia infection and, in fact, may be

desirable as a clear indication that the vaccine has been applied with sufficient vigor. The pressures should be made in the smallest area possible to minimize the size of reaction and resultant scar. $(1/8" \times 1/8" \text{ or } 3\text{mm.} \times 3\text{mm.})$.

The stainless steel "dipstyck" needles will be provided in a ratio of one needle per five doses of vaccine. This compromise was necessary because of budgetary limitations. Needles must be sterilized between vaccinations to prevent the transmission of serum hepatitis and other blood transmissible infections. A simple alcohol lamp can be used to sterilize the needles or they may be boiled for 20 minutes. The needles should be cooled to approximately ambient temperature before inserting them into the reconstituted vaccine.

(2) Linear Scratch Method

The vaccinating tool now used in West Africa for the scratch method is wasteful of vaccine. Approximately 10-20 vaccinations can be done with the amount of vaccine that is provided in the multiple pressure vaccine vial contrasted to 100 or more when the dipstyck is employed. The dipstyck multiple pressure needle may be used for scratch vaccination.

The technique consists of dipping the prongs into the vaccine and then making a scratch approximately 1/4 inch (6.5 mm.) in length to a depth sufficient to produce a slight amount of bleeding. More than one needle stroke may be required to produce a scratch of sufficient depth. The scratch will actually be a double parallel scratch spaced about 1 mm. apart because the needle is two-pronged. Any vaccine remaining on the needle should be smeared into the scratch. Multiple insertions at different sites are unnecessary as it has been clearly shown that with potent

vaccine two insertions offer no advantage over one insertion.

As in the instance of multiple pressure use, needles will have to be reused and sterilized between each use. An alcohol lamp can be used to flame sterilize the needles. Sufficient time must be allowed for the needle tip to cool so that vaccine virus is not heat-inactivated. As groups receiving multiple pressure vaccination in general will be small, there should be time to allow for the cooling of needles between vaccinations. Alternatively, the needles may be boiled for 20 minutes.

At this time, it is unknown how medical personnel in West Africa might adapt to the multiple pressure method. If resistance is encountered, the issue should not be pressed as properly performed scratch vaccination will be effective. To be encouraged, however, is the use of the "dipstyck" for scratch vaccination as this will make vaccine go 10 times farther than with the use of the vaccinating instrument currently used in most countries.

(3) Jet Injector Method

The technique for jet vaccination is described in the jet injector operations manual.

F. Clinical Response to Vaccination

1. WHO Criteria

The clinical vaccination reaction as measured by skin response is to be judged by the criteria set down by the WHO Expert Committee on Smallpox (WHO Tech. Rep. Series No. 283, 1964).

"A successful primary vaccination is one which, on examination after one week, shows a typical Jennerian vesicle."

"A successful revaccination is one which, on examination one week (six to eight days) later, shows a vesicular or pustular lesion or an area of definite palpable induration or congestion surrounding a central

lesion, which may be a scab or ulcer. These reactions should be termed 'major reactions'; all others should be termed 'equivocal reactions.' A major reaction indicates virus multiplication with consequent development of immunity. An equivocal reaction may be the consequence of immunity adequate to prevent virus multiplication or may be an allergic skin response elicited by inactive vaccine or poor technique."

The choice of the one week reading (six to eight days) time is the best compromise for a "one time" reading which is applicable for both primary and revaccination reactions. The one-week reading virtually insures that on a first vaccination attempt early (immediate) reactions are read as equivocal or unsuccessful (no take). Under ideal conditions evaluation of the revaccination response should be done daily to ascertain both the character and temporal peaking of the inflammatory response. Except under experimental conditions, this is totally impractical. Very few if any early (immediate) responses due to allergy will be classified as major reactions when vaccination responses are evaluated at seven days as recommended by the WHO Smallpox Expert Committee.

2. Primary Vaccination

The primary vaccination response occurs in individuals who are non-immune to vaccinia virus and smallpox virus. In addition, persons vaccinated in the past (15 to 20 years) may have lost sufficient immunity to vaccinia virus and will respond with a primary type reaction despite the presence of an old primary vaccination scar.

After primary vaccination, little reaction is seen until the second or third day when a small, red papule appears. By the fifth to sixth day, a vesicle develops which undergoes progressive pustulation, reaching a peak size by the eighth to ninth day after vaccination. A progressive increase in erythema and induration coincides with pustule development. During the pustulation phase, central umbilication occurs followed shortly

by central scab formation which progresses centrifugally. By the eleventh to twelfth day after vaccination the lesion has completely scabbed and inflammatory reaction has subsided. The dried scab separates in 14-21 days leaving a slightly depressed hypopigmented scar. If the pustule should be broken, scabbing will be accelerated. If secondary infection should occur at this time, healing will be prolonged.

Associated with the reaction at the site of vaccination are variable local and systemic symptoms such as local swelling of the arm, axillary lymph node enlargement, fever, malaise and headache. These are considered to be normal components of the primary vaccination response.

Fever usually appears at about the sixth day and subsides by the eighth to ninth day. A fever of 100° F. to 101° F. is normal; rarely does it exceed 103° F.

Headache and malaise usually appear and ebb coincident with fever.

These systemic signs and symptoms are thought to be related to the viremic phase of vaccination, although the few attempts that have been made to isolate vaccinia virus from blood during this interval have been unsuccessful. Swelling of the arm, axillary lymph node enlargement with attendant discomfort or pain usually subsides by the ninth to tenth day. In general, local and systemic symptoms associated with primary vaccination are more severe in adults than young children.

3. Revaccination

The skin response following revaccination is variable and depends upon the immune and allergic status of the individual. In general, the evolution of the skin response is accelerated compared to that observed in a primary response. The acceleration of response is presumably due to the influence of hypersensitivity or allergy to vaccinia virus induced at the time of primary vaccination.

Traditionally, the two basic revaccination responses are known as the early (immediate) type and the "vaccinoid" (accelerated) type.

a. The Early Response

The early reaction begins with the appearance of a pruritic papule within 24 hours after vaccination. The erythematous inflammatory response reaches a peak before 72 hours and rapidly subsides. By seven days evidence of erythema has either completely disappeared or is barely visible. The early response is rarely associated with vesiculation. This reaction indicates either a high degree of immunity to the vaccinia/ variola group viruses or may mean only an allergic response to vaccinia virus; a similar reaction may be elicited by impotent vaccine or faulty vaccination technique. In some cases, the early response may be associated with a neutralizing antibody booster response, but there is no way to ascertain that this has happened on the basis of the skin response. Under the WHO definition of revaccination responses, this type of reaction is classified as an equivocal response (no take or not successful), which means that immunity cannot be implied. All persons responding with an equivocal reaction should be revaccinated (when possible) with known potent vaccine by good technique.

b. The Vaccinoid Response

The vaccinoid reaction (accelerated or major reaction) may become apparent as a papular erythematous response within 48 hours after revaccination but does not reach a peak of reaction until 72 hours after revaccination. The peak of erythema and induration may come at any time after the third day up to the ninth day. The inflammatory response is associated with development of a vesicle, pustule, or central necrotic area, which proceeds to scab formation. The central lesion may be quite small, 2-3 mm. in diameter or larger than 5 mm. neutralizing antibody boost is virtually assured with this type response.

By WHO Expert Committee on Smallpox definition, this type of response when present by the sixth to eighth day after revaccination is classified as a <u>major reaction</u> and denotes that a successful vaccination with virus multiplication and a subsequent boost in immunity has occurred.

Generally, there are few systemic symptoms following revaccination unless previous immunity has waned to the point where the revaccination reaction approaches a primary-type response. The main discomfort associated with the revaccination reaction is pruritus at the vaccination site due to vaccinia virus hypersensitivity.

G. Antibody Response After Vaccination

Antibodies to the vaccinia/variola group of viruses appear soon after vaccination. Three types of antibodies can be measured in the blood serum: neutralizing antibodies, hemagglutination inhibition antibodies (HI), and complement fixation (CF) antibodies.

1. Primary Vaccination

After successful primary vaccination, neutralizing and HI antibodies appear by about the fourteenth day in virtually 100 percent of subjects with clinical takes. Complement-fixation antibodies can be detected in fewer than 20 percent. Neutralizing antibodies may be detectable for more than 20 years after vaccination in some individuals but there is great individual variability and, in some cases, no antibody may be detectable after 12 months. HI and CF antibodies usually can no longer be detected after 6-12 months. (McCarthy, K., Downie, A.W. and Bradley, W.H., J. Hyg. (Lond.) 56:466, 1958; Millar, J.D., Roberto, R.R., Wulff, H., Manuscript in preparation.)

2. Revaccination

Following successful revaccination, the neutralizing antibody response is accelerated and rises to much higher levels than is normally elicited after primary vaccination. The antibody booster response can be detected by about the seventh day after vaccination. Little is known regarding the neutralizing antibody decay pattern after revaccination; however, it is presumed that antibodies persist for many years. HI and CF booster responses are both poor after revaccination. (McCarthy, K., Downie, A.W., and Bradley, W.H., J. Hyg. (Lond.) 56:466, 1958; Millar, J.D., Roberto, R.R., Wulff, H., Manuscript in preparation).

The relationship between level of humoral antibody and protection against smallpox in-vivo has not been demonstrated. Although there are no data providing satisfactory information on the relationship between antibody level and immunity to smallpox, it is the concensus of laboratory workers in this field that neutralizing antibody is closely correlated with immunity. However, a few cases are on record where a high level of neutralizing antibody measured shortly before infection or within two days after onset of clinical illness failed to prevent smallpox. (Downie, A.W., Lancet 1:419, 1951; McCarthy, K., et al. J. Hyg. (Lond.)56:479, 1958).

In epidemic situations successful revaccination within the first few days after exposure will usually prevent or greatly modify clinical illness as the acceleration of the immune booster phenomenon blocks multiplication and dissemination of smallpox virus. In such situations the WHO Expert Committee has recommended multiple inoculation at two or three sites.

3. Influence of Maternal Antibody on Primary Vaccination Response

Passively transferred maternal antibodies which are present for approximately six months after birth do not significantly interfere with the success of primary vaccination if potent vaccine is employed. Espmark

(A. Espmark, Acta Pediatrica Scandinav. 54:149 and 341, 1965) has shown that, using vaccine with a titer of $10^{8.0}$ TCID $_{50/\mathrm{ml.}}$, no significant differences in take rates or antibody responses could be demonstrated between infants less than 10 weeks of age as contrasted with infants 5-12 months old.

Smallpox Vaccination Take Rates Obtained with Serial Dilutions of Vaccine in Two Age Groups of Infants*

Dilution of	Age <10 wks.	draw Leui	Age 5-12 Months	
Vaccine	Takes/Total in Group	% Takes	Takes/Total in Group	% Takes
Undiluted**	63/67	94		
1:3.16	53/64	83	apinala bua biai	
1:6	59/67	88		
1:10	51/66	77	37/37	100
1:31.6	51/79	65	46/50	92
1:100	23/90	26	48/67	72
1:316	2/49	4	19/57	33
1:1000	A 14 14 15 15 15 15 15 15 15 15 15 15 15 15 15		9/29	31

* (Adapted from A. Espmark, Acta Pediatrica Scandinav. $\underline{54}$:149, 1965) ** Titer of undiluted vaccine $10^{8\cdot0}$ TCID $_{50/ml}$. Multiple pressure technique

employed.

Neutralizing Antibody Against Vaccinia Virus in One Month Old and 9-12 Month Old Infants Before and After Successful Primary Vaccination*

	A PARTY NAMED IN	Age 1 Month					Age 9-12 Months					
<u>Time</u>	Neut. Tite	er <1:10	1:10	1:32	1:100	<1:10	1:10	1:32	≥1:100			
Prevaccinati	ion	2	9	3	0	14	2	0	0			
1 Month Post	t-Vacc.	0	2	9	3	0	2	4	10			
9-12 Months	Post-Vacc.	0	2	12	0	0	3	10	3			

* Titer of undiluted vaccine 107.5 TCID50/ml. Multiple Pressure Technique

(Adapted from A. Espmark, Acta Pediatrica Scandinav. 54:341, 1965)

From these data it would appear that there is a measurable depressant influence of maternal antibody, but that it can be overcome with highly potent vaccine. In endemic areas, it would seem advisable, when possible, to revaccinate infants who were initially vaccinated younger than six months of age to insure induction of immunity.

H. Duration of Immunity Produced by Successful Vaccination

There is surprisingly little documented specific information on the duration of immunity to smallpox after vaccination.

1. Variola Major

After successful primary vaccination, immunity to variola major is almost complete for three years, but as with all biological phenomena there are individual variations. Breakthroughs within the three-year period after vaccinations have been recorded, although such cases are rare and clinically mild. C. W. Dixon (WHO Expert Committee on Smallpox, WP/7, December 11, 1963) has developed a probability scale of susceptibility to smallpox related to the number of years since primary vaccination.

No. of Years Since Primary Vaccination	Probability of Contracting Smallpox Compared to the Unvaccinated
ears also also a la locato a	1:1,000
3	1:200
10	1:8
20 70 12 12 12 12 12 12	1:2
> 20	Little to no protection.

However, it should be emphasized that smallpox illness within 10 years after successful primary vaccination is generally mild; the individual, however, may still serve to transmit the disease. Mortality in smallpox patients successfully vaccinated many years before is less than in the unvaccinated, although deaths do occur.

Comparison of Mortality Rates in the Vaccinated and Unvaccinated Based on Hospital Admissions to the Metropolitan Asylums Board Hospitals during 1901-1904*

	V	accina	ted	Unvaccinated or Doubtful				
Age in Yrs.	Admitted	Died	Case/Fatality Rate - Percent	Admitted	Died	Case/Fatality Rate - Percent		
-10	143	2	1.4	1,441	459	31.9		
11-20	1,218	23	1.9	761	166	21.8		
21-30	2,675	144	5.3	374	129	34.5		
31-40	1,861	247	13.3	180	80	44.4		
41-50	893	174	18.2	102	57	55.9		
51-60	311	55	17.7	73	31	42.5		

*Adapted from Topley and Wilson v. 2, pg. 2281. Williams and Wilkins Co. 1964.

Assuming that most of this population received vaccination in early childhood and were not subsequently revaccinated the data imply gradually declining protection to infection and an increasing case-fatality ratio.

After revaccination, protection against clinical disease is undoubtedly greater; however, specific data are not available. In medical and nursing personnel revaccinated at regular intervals, infection is extremely rare. In the Indian Army, revaccination is required at least every three years. A case of smallpox has yet to be reported in Army personnel, despite undoubted frequent exposure to smallpox. (Personal communication, H. Gelfand)

2. Variola Minor

Immunity to variola minor after successful primary vaccination persists for a much longer period than for variola major. In J. Pickford Marsden's analysis of 13,686 variola minor cases which he personally attended, only seven cases gave evidence of having been vaccinated within 10 years and no smallpox hospital personnel contracted the disease. Even 20-30 years after successful vaccination, there appeared to be considerable immunity to clinical infection.

Variola minor probably confers little more immunity than vaccination against an attack of variola major. In areas where both variola major and minor occur, reports of a second attack of smallpox in a patient may suggest that the initial illness was variola minor.

I. Indications for Vaccination

Vaccination should be offered to all persons of all ages except as noted under contraindications. If an eradication program is to be successful, the highest rates of immunity possible must be achieved in all segments of each population unit that are reached by vaccination teams. A special effort should be made to reach all high risk persons such as hospital workers, military and police personnel, immigration and border control workers, and international transport workers and travelers.

J. Contraindications to Vaccination

1. General

In the context of a smallpox eradication program where national borders are poorly defined and where populations are highly mobile, contraindications to vaccination as they would obtain in non-endemic areas do not apply.

In areas where smallpox has <u>not</u> been endemic for a number of years, the generally accepted contraindications to routine primary vaccination are:

- (1) immunologic disorders, (2) neoplastic disorders involving the reticuloendothelial system such as leukemia, lyphomas, Hodgkins disease,
- (3) conditions involving the prolonged use of corticosteroids, antimetabolite drugs, or radiation therapy, (4) eczema in the child to be vaccinated or in siblings with whom close contact cannot be avoided, and (5) pregnancy.

In weighing possible contraindications to vaccination in endemic smallpox regions, consideration must be given to the risk of smallpox as contrasted to the risks associated with vaccination. Almost invariably, smallpox will be found to pose the greater risk. If it is decided that certain conditions should represent contraindications to vaccination, the problem of the identification of such conditions immediately arises. In

the mass programs, individuals must be vaccinated rapidly by vaccinating personnel with little medical training. Unless the conditions of concern are grossly apparent, the screening procedure will not be feasible. If contraindications are not simply and specifically defined, large numbers of people may be excluded in error and the probability of eradication seriously compromised. Even in the United States, where physicians are directly responsible for vaccination, 50 percent of complications occur in persons with theoretically detectable contraindications.

In West Africa, contraindications to vaccination should be reduced to the minimum. This applies both to countries in which smallpox is currently being reported and to those which have not reported smallpox for several years. Because of the high mobility of African populations, reintroductions of smallpox into smallpox-free areas may be expected as a common phenomenon. Unless a high proportion of smallpox immunes is maintained reestablishment of endemic foci will occur. After the attack phase throughout West Africa has been successfully completed, it will then be possible to devote greater attention to contraindications.

Conditions which should be considered are discussed below. Policies will need to be worked out with national medical officials and simple, specific instructions issued.

2. Considerations Regarding Contraindications to Vaccination

a. Immunologic Disorders, i.e. dysgammaglobulinemias

In practically all instances, persons with such disorders will not be identifiable. In most instances, children with these disorders will have died of other causes during the first months of life.

b. <u>Leukemia</u>

Leukemia is a rare disease; in children and young adults, death occurs within months to a year. Except in cases where patients have been hospitalized with this diagnosis, such persons will not be identifiable. When the diagnosis is known, leukemics should not be

vaccinated but the rarity of the diagnosed disease makes it impractical to screen vaccinees routinely during the mass campaign.

c. Neoplastic Disorders of the Reticuloendothelial System

Cancers involving the reticuloendothelial system may be associated with serious vaccination complications. The number of persons in this category will be very small and, in general, unidentifiable except when hospitalized. Children with suspected Burkitt's Tumor (recognizable by a large tumor of the jaw) should not be vaccinated except in epidemic situations.

d. Immuno-suppressant Therapy: Treatment with Corticosteroids, Antimetabolite Drugs (anti-cancer medications) and Radiation Therapy

Again, it is highly unlikely that persons receiving these treatments will be found outside the hospital environment. Vaccination should be deferred for a period of several weeks after termination of therapy.

e. Skin Disorders

(1) Eczema

Children with eczema sometimes develop eczema vaccinatum following vaccination or exposure to another vaccinated person.

This condition may occasionally be fatal and may develop in persons with a history of eczema but who's skin appears normal at the time of vaccination. Eczema is believed to be much less common in Africans especially in tropical areas than in the United States or Europe. Morley describes it as "extraordinarily uncommon" in West Africa (personal communication). Trowell and Jelliffe regard it as a rare disease among the lower socioeconomic groups in the tropics (H. C. Trowell and D. B. Jelliffe, Diseases of Children in the Sub-tropics and Tropics, Edward Arnold, Ltd., London, 1958, page 571). These authors note two types of infantile eczema, both tending to be chronic. The first, most commonly involves the face especially the cheeks in front of the ears. The

second variety, considered to be very, fare in the tropics, involves flexures of the axillae, knees and elbows.

An eczematous child need not be vaccinated to contract eczema vaccinatum since the virus can be inoculated from a vaccinated sibling or playmate through close contact. In the village setting with its crowding and communal nature such contacts will be unavoidable when the remainder of the villages are vaccinated, therefore the eczematous child's risks of acquiring a serious vaccinial infection will be virtually identical whether or not he is vaccinated.

To avoid exposing the eczematous child to contact with vaccinia virus would necessitate either that the child be secluded for two weeks from the village or that the entire village be left unvaccinated. Neither of these alternatives is practicable. Clearly there is no ideal solution to the problem posed by the eczematous child in a mass smallpox vaccination program where neither isolation nor the administration of protective vaccinia immune globulin are feasible. If the child is vaccinated he runs the risk of developing eczema vaccinatum; if left unvaccinated he similarly runs this risk but in addition is denied protection against smallpox. Since mobile vaccinating teams will have little competence in the diagnosis of dermatologic conditions, it would seem preferable to consider eczema a contraindication of vaccination only when the condition is gross and obviously active. Further, it should be realized that exclusion of such children from vaccination does not necessarily diminish their risks of acquiring eczema vaccinatum.

(2) Scabies and Pyoderma

Both scables and pyoderma are common in the tropics. In general, these diseases tend to be localized to a relatively small skin area. Experience during jet vaccination studies in Tonga and the Federal

Territory of Amapa, Brazil, has shown that secondary infection of this type of lesion with vaccinia virus occurs rarely, if at all. In both areas, many children with scabies and pyoderma were vaccinated without complications.

(3) Leprosy

There is some evidence to indicate that both smallpox and vaccination are more severe in persons with leprosy. (Webster, I.A., W. African Med. J. 8:32, 1959; Browne, S.G., et al, Leprosy Review 33:252, 1962).

Primary vaccination may provoke the erythema nodosum leprosum reaction (ENL) or neuritis in leprous patients with either the lepromatous or tuberculoid form of the disease, although it is more common in those with the lepromatous form. (In the Webster series, 82 percent with the lepromatous form developed ENL following primary vaccination while only 25 percent of those with the non-lepromatous type did so.) In the non-lepromatous group, almost all had been treated for ENL or neuritis at some time previously. In revaccinees, the likelihood of an ENL reaction is small unless the patient is usually subject to such reactions. The ENL exacerbations after vaccination have an incubation period of about 7-10 days and cannot be distinguished from the reaction which occurs spontaneously or during the course of leprosy treatment. Most patients have recovered without sequelae, although one death occurred in a patient who died several months later of fulminating lepromatous disease. No mention is made of the medication status of these patients; it can be assumed that all were probably receiving some form of therapy since they were domiciled in leprosaria.

Thus for lepromatous patients in leprosaria it would seem best to defer primary vaccination until the disease converts to the tuberculoid phase. When leprosy patients are recognized in the community during mass campaign activities, they should be referred for treatment before vaccination is attempted. In epidemic situations, vaccination should not be withheld unless isolation of leprosy patients from contact with smallpox can be assured.

(4) Miscellaneous Dermatologic Conditions Where Extensive Skin Areas
Present an Open, Denuded Skin Surface, i.e., Burns, Exfoliative
Dermatitis, Etc.

Such persons should not be vaccinated.

f. Malnutrition

(1) Kwashiorkor and Marasmus

Vaccination probably should be withheld from children with frank kwashiorkor or marasmus because of the general decreased ability of these children to control infections and because of the extensive dermatitis associated with kwashiorkor.

g. Severe Acute Illnesses and Terminal Disease

Although no increased risk has been documented as a result of vaccinating persons severely acutely ill or with terminal illnesses (other than reticuloendothelial tumors), it would be prudent, in general, to avoid vaccinating such persons. If death should occur shortly after vaccination, this might be attributed to the vaccination when, in fact, another cause was responsible. Such deaths associated in time with vaccination might result in adverse acceptance of vaccination.

h. Pregnancy

In smallpox endemic areas, pregnancy is not a contraindication to vaccination. Smallpox in the pregnant woman is associated with increased

mortality for both mother and fetus, whereas following vaccination, the risk of trans-placental transmission of vaccinia virus to the fetus is extremely low. No fatalities due to smallpox vaccination in the pregnant woman have been reported.

SMALLPOX IN THE PREGNANT FEMALE AS COMPARED WITH NON-PREGNANT FEMALES AND ADULT MALES IN THE SAME AGE GROUP (15-45 yrs.) SEEN OVER A 12-MONTH PERIOD IN MADRAS, INDIA*

	Pregnant Women (94)	Non-Pregnant Women (348)	Adult Males (502)
Overall Case Fatality Rate	27.6%	8.3%	6.1%
a. Vaccinated	20.7%	4.2%	3.0%
b. Unvaccinated	75.0%	25.7%	24.0%

*After Rao, A. R., et al, J. Indian Med. Assoc. 40:353, 1963.

The increased fatality rate in pregnant women has been directly related to an increased incidence of the hemorrhagic and malignant-confluent forms of smallpox. In the Rao study the stillbirth rate of pregnant women with smallpox was 43.9 percent for births classed as premature and 10.7 percent for full-term births. ("Normal" rates in this area for pregnant women without smallpox are not stated).

Fetal vaccinia is rare, but does occur. There are 17 instances of fetal vaccinia recorded in the world literature. The prior vaccination status of the mother is known in 13 of these cases; 11 of the 13 were in non-immune pregnant women. The other two were revaccinees but vaccination had been done 15 to 20 years previously.

Data from studies dealing with vaccination and abortion, still-birth, and prematurity are conflicting. Eight studies have been reported on this subject. (Appendix 1) Six suggest that vaccination has no effect on these outcomes, while two studies indicate an increase

in abortion rates when vaccination is done during the first trimester of pregnancy. The latter two studies (McArthur, P., Lancet 2:1104, 1952; Bieniarz, J., et al., Polski Tygoodnik Leharski (Warsaw) 11: 2183, 1956), however, employed no control group (McArthur) or non-comparable controls (Bieniarz). None of the studies implicate vaccinia virus as a teratogen.

Other considerations militate against considering pregnancy as a contraindication for vaccination in smallpox endemic areas: (1) the large proportion of the female population of child-bearing age who might not be vaccinated if pregnancy were considered a contraindication, and (2) the virtual impossibility of determining the pregnancy state in a mass campaign until abdominal enlargement became readily apparent, i.e. well after the third month of gestation.

3. Summary

In summary, there are few conditions for which smallpox vaccination is contraindicated in West Africa. In practice, the only persons who might be readily and rapidly identified by vaccinating teams as having conditions for which vaccination might be contraindicated are those with extensive skin disorders (severe eczema, lepromatous leprosy, kwashiorkor, burns, etc.) and those with severe illnesses of an acute or terminal nature. It should be recognized, however, that contact transfer of vaccinia virus to these persons may take place because of the intimacy of living arrangements, both in urban areas and communal villages. Pregnancy should not be considered a contraindication but rather an indication for vaccination since the prognosis for both mother and fetus are much worse should smallpox be contracted. Age per se is not a contraindication. All age groups, newborns through the aged, should be vaccinated. In epidemic situations, there are no contraindications to vaccination unless protective isolation of susceptibles can be assured.

K. Simultaneous Administration of Smallpox Vaccine with Other "Live" Immunizing Agents

Simultaneous administration of smallpox vaccine with measles vaccine and yellow fever vaccine is discussed in the section of this manual dealing with measles vaccine.

1. Simultaneous BCG and Smallpox Vaccine Administration

BCG is another immunizing agent which is commonly administered to children in West Africa. There is a great deal of interest on the part of African health workers in the feasibility of simultaneous administration of BCG and smallpox vaccines.

There have been two reports published regarding simultaneous vaccination with BCG and smallpox vaccine. (Moodie, A.S., and Cheng, G.K.K., Tubercle, Lond. 43:155, 1959; Lin, H.T., Bull. WHO 33:321, 1965).

Moodie and Cheng reported on concurrent BCG and smallpox vaccination (both by multiple pressure technique) in 300,000 newborn infants in Hong Kong. No complications occurred. They concluded that BCG had no effect on the primary take rate while the Mantoux conversion rate and BCG reactions compared favorably with results others have reported when BCG was given alone.

In the sub-group, the following results were obtained:

SMALLPOX AND BCG VACCINATION RESULTS IN NEWBORN INFANTS GIVEN SIMULTANEOUS BCG AND SMALLPOX VACCINATION*

	Group	No. Newborns	Primary Smallpox Vaccination Take Rate	BCG Conversion Rate (Mantoux Test 5 mm.)
1.	Smallpox and BCG at Birth	486	9 2%	95%
2.	Smallpox only at Birt	h 500	94%	holony i
3.	BCG at Birth Smallpox at 3 weeks	523	the aged, should be	97%
	*Adapted from Moodie	and Cheng,	Tubercle, Lond. 43:1	55, 1959.

A second study (Lin) was conducted in Taiwan in 696 newborns divided into three equally sized groups and vaccinated by one of the following schedules: (1) simultaneous vaccination with smallpox and BCG vaccines, (2) BCG only, and (3) smallpox vaccine only. Smallpox vaccination was done with liquid lymph by the double-scratch technique while BCG was administered by intradermal injection with needle and syringe. The vaccines were given in separate arms. No differences were observed with respect to smallpox vaccination between the group given the vaccines simultaneously and the group given smallpox vaccine alone. Primary take rates, the frequency distribution of the size of vaccination reactions and the response to revaccination at 12 weeks were the same in each group. Tuberculin tests at 12 weeks gave a normal distribution in the size of tuberculin reactions (5 TU of PPD RT 23 with tween-80) with a mean of 11.94 mm. for the "simultaneous" group and a mean of 12.19 for the "BCG only" group. In the "smallpox only" group, all tuberculin reactions were less than 9 mm., the great majority being 0-3 mm. There were no complications following BCG vaccination. There were five mild smallpox vaccination complications; three in the "simultaneous" group (two generalized vaccinia, one large local reaction) and two in the "smallpox only" group (one generalized vaccinia, one large local reaction). All recovered without difficulty. Lin concluded that simultaneous vaccination with BCG and smallpox vaccines was a safe and effective procedure.

RESULTS OF PRIMARY SMALLPOX VACCINATION AT ONE WEEK*

		Prima	ry Take	No	Take
Group	No. Infants	No.	%_	No.	_%
Simultaneous Smallpox and					
BCG	251	190	75.7	61	24.3
Smallpox Only	200	152	78.5	43	21.5

DISTRIBUTION OF TUBERCULIN REACTIONS BY SIZE AT 12 WEEKS*

	Simu	ltaneous Group					
Size of Reaction	Total	Those with take on initial small-pox vaccination	0	llpox nly oup	BCG Only Group		
(Diameter in mm.)	No. %	. <u>No</u> . <u>%</u>	No.	_%	No.	%	
0-5	16 7.3	14 8.3	167	95.4	11	5.1	
>5	209 92.7	156 91.7	8	4.6	203	94.9	
Total	225 100.0	170 100.0	175	100.0	214	100.0	
Mean Diameter	11.94 mm	. 11.90 mm.	-lann	anyeg g	12.	19 mm.	

*Adapted from Lin, Bull. WHO 33:321, 1965.

The reason for the low take rates in both the "simultaneous" and "smallpox only" groups is not readily explainable; however, it was uniformly low in both groups, indicating that BCG did not have any effect on the results of smallpox vaccination. A single lot of vaccine was employed and a rabbit potency test following the study showed no decrease in titer. A possible explanation for the low take rates was that in the latter months of the study ambient temperatures were usually above 90°F. and during the clinics vaccine was removed from the refrigerator and held at the ambient temperature during working hours. A single nurse carried out all vaccinations. Inquiries of mothers failed to reveal that any of them had been revaccinated during pregnancy. In contrast, in the Moodie and Cheng study noted previously, the primary vaccination take rates in "simultaneous" and "smallpox only" groups were 92 percent and 94 percent, respectively.

2. BCG Vaccination by Jet Injection

A single report on BCG vaccination by intradermal jet injection has appeared in the literature. In this study, the Dermo-jet injector was employed (Griffiths, M.I., et al, Lancet $\underline{2}$:399, 1965). The authors found that administration of BCG vaccination by jet injection was highly

acceptable to school children and that the time required for vaccination was reduced to one-half that needed for inoculation by syringe. The BCG vaccination lesions produced by Dermo-jet inoculation showed wider variation in size and tended to be more papular and less frequently vesicular than those produced by inoculation with syringe. No complications were reported.

LOCAL REACTION TO BCG VACCINATION*

		Size of Vaccination Lesion						
Group		Syri	nge	Jet Injector				
	Weeks After Vacc.	No.	Mean Size (mm.)	No.	Mean Size (mm.)			
1	6	271	5.3	239	5.1			
2	6	156	6.0	156	7.2			
3	6 8–10	105 119	7.1 7.5	114 116	7.3 6.7			

RESULTS OF TUBERCULIN SKIN TESTING WITH 10.TU of PPD AFTER BCG VACCINATION*

			E & Marie	Results of M	lantous	10 TU	
			Syrir	ige		ector	
Group	Weeks After Vacc.	No.	% Pos.	Mean Indu- ration (mm)	No.	% Pos.	Mean Indu- ration (mm)
1	6	271	100	16.2	239	100	15.0
2	6	156	100	16.0	156	100	16.9
3	6 8 – 10	105 119	97 99	16.6 17.7	114 116	99 99	16.7 16.2
Totals		784			758		

*Adapted from Griffiths, M.I., et al, Lancet 2:399, 1965.

Use of the Ped-O-Jet for intradermal BCG vaccination should give comparable results to that achieved with the Dermo-jet injector. Studies with the Ped-O-Jet are needed.

APPENDIX 1
SUMMARY OF STUDIES DEALING WITH SMALLPOX VACCINATION AND OUTCOME OF PREGNANCY

			Stage of	Conge		C+411	Birth	s Abort	fons	Prema	turity		natal aths
Study	Methodology	No. Pregnant Women	Pregnancy When Vacc.	No.	malities _%_	No.	<u>%</u>		_%_	No.	_%_	-	_%_
Urner, 1927, USA	Prospective	Vacc. 129 No controls	12-39 wks.	0		0		0		0		-	-
Greenberg, et al 1949, USA	Retrospec-	Vacc. 4,172 Not Vacc. 2,1	1-12 wks.	68 30	1.63 1.37					343 185	8.2 8.5		
Bellows, et al 1949, USA	tive	Primary take 36 Accel. take 21 No reaction 14 Not. vacc. 17	0)1-37 wks.	8 8 7 4	2.3 4.7 3.8 2.2	(354) ¹ 4 (207) 6 (144) 9 (169) 8	4.2	(200) ² 7 (129) 3 (99) 5 (103) 4	2.4				
MacArthur 1952, Scotland		Vacc. (69 (67 Tot. Vacc. 203 No controls	1-12 wks. 13-24 wks. 24+	1 0 0 1	1.5	5 1 0 6	7.5 1.4 - 3.0	11 0 0 11	16.4	1 3	1.5 1.4 4.5 2.5	0 0 1 1	- 1.5 1.5
Bieniarz, J. et al 1956, Poland		Vacc. 1,270 Not Vacc. 3,51	3	1,000		-	-	2-3 fold crease tion rat control when value	in ab te ov grou cc. d	or er p one			
Abramowitz, 1957, S. Africa	Retrospec- tive Va	(Take 510 acc(No Take 611 (Not Vacc.211		8 16 3	1.5 2.6 1.5	11 10 3	2.1 1.6 1.5	= =	-			8	1.2 1.3 1.5
Liebeschuetz 1964, England	Retrospec- tive	Vacc. 157 Not Vacc. 1,65	1-20 wks.	3 22	1.9 1.3	3 21	1.9	8 74	5.1 4.5		-	-	-
Bourke & Whitty 1964, Ireland	Prospec- tive	Vacc. 114 (54 in first trimester)	3	2.5	3	2.5	1 4	0.9		-	-	-

- 1. Still birth rates among women who had reached the fifth month of pregnancy without an abortion.
- 2. Abortion rates among women less than five months pregnant at the time of vaccination.
- 3. Control group not comparable. Eighty percent were pregnant in the preceding year.
- 4. A "take" is defined as the presence of a vesicle and scab, anything less was regarded as "no take."

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AREAS OF INTEREST FOR FIELD RESEARCH AND INVESTIGATION

Introduction

In view of the proliferation of medical research during recent decades, it is perhaps surprising that much epidemiologic information concerning the viral exanthems is either lacking or is based on broad interpretations of incomplete or inadequate data. A number of important epidemiologic aspects remain to be described and clarified.

The very theories of smallpox eradication and measles control are based on certain assumptions, for the most part resulting from processes of logic; few, if any, of these considerations have been subjected to critical scientific scrutiny in the field.

More specifically, little is known regarding patterns of occurrence of smallpox, measles, chickenpox, and other viral exanthems in Africa. Anecdotal experiences would suggest that, in Africa, these diseases may behave quite differently than the same diseases occurring in more industrially developed areas. The interactions of nutrition, chronic disease, climate and the high incidence of parasitism, in variable and distinctive patterns of social organization, suggest that experience gained elsewhere does not necessarily permit extrapolation to Africa.

In the context of the Smallpox Eradication/Measles Control Program in West Africa, a unique opportunity is offered for the epidemiologic study of these diseases. It is perhaps safe to say that almost any sound epidemiologic information obtained will be original.

The purpose of this section is to point out in general terms broad gaps in our present understanding of the occurrence and transmission of these diseases, and to outline ways in which the various theories of eradication might be subjected to scientific scrutiny. In addition, reference will be made to several other areas where more information is needed concerning smallpox control and mass immunization practices. It is perhaps superfluous to add that the following descriptive list is only a partial one, and can be extended indefinitely by the inquiring mind.

Many of these studies can be carried out by one or a few individuals alert to the opportunities presented by epidemic circumstances, single cases with unusual epidemiological histories, etc. Some, however, require the development of fairly sophisticated protocols with carefully selected subjects and controls, etc. and involve substantial laboratory work. If a study of this latter type is contemplated, it is important that RPO and Headquarters Staff be consulted prior to its initiation to insure that the study design is optimal, that it does not unnecessarily duplicate efforts initiated elsewhere, to ascertain the need for and the possibility of providing supplementary personnel and to insure that our laboratory capacity will not be overtaxed. The RPO should be kept currently informed regarding the development and progress of all studies.

A. Epidemiology of Viral Exanthems in West Africa

A considerable amount of important information can be obtained simply from observation of the basic patterns of disease occurrence and the application of simple epidemiologic analysis. The principal areas of interest are summarized below:

- 1. Seasonal patterns of occurrence within the four climatic regions of West

 Africa.
- 2. Age and sex distribution of cases.

Suggestions have been made that measles and chickenpox occur in patterns more or less different from those documented in more industrialized societies, specifically that measles, for uncertain reasons, occurs at a much younger age while chickenpox is comparatively prevalent among adults. The age distribution of smallpox cases in West Africa is very poorly described. Variations in smallpox incidence by sex may provide an important clue to differences in vaccine (or vaccination program), acceptance by sex or to relative differences in type or frequency of exposure.

3. Urban versus rural disease concentrations.

On logical grounds, principally, it has been assumed that smallpox and, to a somewhat lesser extent, measles and chickenpox are "crowd diseases," that their endemic persistence is dependent upon adequate conglomerations of people. On the other hand, many health workers with experience in Africa believe that smallpox occurs commonly and that the virus can persist in remote areas with only small, scattered population groups - its continued presence made possible by the high mobility of Africans. An analysis of the prevalence of these diseases by size of urban concentration and descriptions of outbreaks in rural areas would provide substantially new information on endemic patterns of the disease. In the context of smallpox eradication in Africa, as distinct from mere control, it is obviously necessary that we know whether smallpox will disappear spontaneously in remote areas after urban foci are eliminated or whether such remote areas require the same degree of intensive vaccination.

4. Case fatality ratios.

Information available on measles mortality in West Africa, largely based on observation of hospitalized cases, suggests that this disease is much more lethal than measles occurring elsewhere in the world. This apparently higher mortality has been attributed to many factors, principally those bearing on nutrition and prevailing chronic disease. The establishment of realistic case fatality ratios in different socio-ecologic conditions is required to substantiate this.

With respect to smallpox, the establishment of case fatality ratios, in conjunction with appropriate virologic studies, is required to ascertain the relative importance and frequency of variola major, variola minor, and intermediate strain disease in Africa.

B. Specific Epidemiologic Indices Assessable Without Laboratory Facilities

Below are listed a number of areas for epidemiological investigation where present knowledge is either imprecise, inadequate, or requiring confirmation in the African setting:

1. Index of infectivity of smallpox.

An index of infectivity of various diseases based on the "susceptible exposure attack rate" in families has been effectively used by Simpson¹. This has permitted a comparison of the infectivity of various viral diseases in industrialized areas. Such a rate has never been adequately developed for smallpox, nor for other exanthems, in Africa. Where smallpox is endemic, we have the opportunity to obtain such information based on the study of the disease in family units. This information would permit confirmation or rejection of the hypothesis that smallpox is a highly infectious disease, and would provide a means of ascertaining whether infectivity differs according to strain.

2. Precise information on the incubation period.

The incubation period of smallpox is felt to be a highly consistent phenomenon, hovering around 12 days. Most such information is based on the average time interval between cases in <u>outbreaks</u>. This interval between cases can be due, however, not only to the incubation period but also to duration of infectivity. In most outbreaks, certain cases can be found which, through circumstance, result from "brief and only-possible" exposures. Such cases provide direct information on the incubation period and permit study of its variability. A series of as few as 15-20 well-documented incubation periods resulting from "brief and only-possible" exposures would permit a better determination of the range of incubation period of smallpox than now exists.

3. Duration of infectivity of smallpox cases.

Laboratory and clinical data suggest that smallpox may be potentially transmissible from the first 24 hours of illness until the last crusts are disposed of. However, the frequently observed intervals of 12-14 days between related cases in outbreaks suggest that the actual period of infectivity is substantially less than the potential one. Careful evaluation of cases in which the circumstances of contact with subsequent cases have been "brief

and only-possible" exposures may provide more precise information on the effective infectivity of the disease. See Dixon² for a full discussion of this subject and Simpson³ for the methodology of assessing the infectious period.

4. Type of contact resulting in transmission.

Data from European and American outbreaks suggest that close personal contact is responsible for most transmission of smallpox; the type of contact frequently documented is intimate, person-to-person contact as in family exposure or in hospital settings. There are, however, disturbing exceptions to the "close personal contact" exposure in which transmission has been explained only by long-range aerial spread. Verification in detail of apparent "jumps" outside the limit of immediate, person-to-person contact must be documented. Such documentation would also permit evaluation of the relative importance of the contaminated environment, such as the household or hospital room, relative to direct personal contact.

5. Duration of protection afforded by vaccination before contact.

Despite its enormous importance, the duration of protection from disease following successful vaccination is only incompletely known. Even more poorly understood is the effect of previous vaccination on the reduction of infectiousness in the person who develops modified smallpox, i.e. the secondary attack rate resulting from the case who had been previously vaccinated as compared to that resulting from the unvaccinated case. In any outbreak, careful documentation of the vaccinal status of cases and non-cases in the same household may provide evidence bearing on the first problem, i.e. the duration of vaccine effectiveness, and careful documentation of the vaccinal status of the first case in relation to secondary attack rates in household associates may provide evidence bearing on the comparative infectiousness of cases previously vaccinated and thus presumably partially immune.

6. The influence of vaccination after exposure on prevention and amelioration of disease.

This area is still clouded with controversy. Serologic evidence suggests a rapid response to revaccination in persons previously vaccinated, which should occur sufficiently soon to prevent or ameliorate smallpox in such persons. On the other hand, it is generally accepted on anecdotal evidence that vaccination or revaccination after the 7th day following exposure exerts no effect on the subsequent development of disease. In any outbreak, vaccination of contacts is likely to provide a ready-made situation for analysis of this effect. Careful documentation of dates of contact and dates of vaccination, coupled with evidence of previous vaccination status, should permit a scientifically acceptable resolution of the problem.

7. Influence of social class and living conditions.

As pointed out by Dixon² (p. 314), the principal influence of social class on the epidemiology of the disease in western nations has revolved around the relative frequencies of vaccination in the various social groups. The influence of housing accommodations and crowding factors are not clearly understood. In areas where little vaccination has been done and where social class is not a determinant of the distribution of vaccine, opportunities should exist to document whether conditions of crowded or unique housing arrangements influence the transmission of the disease.

8. The importance of various types of human mobility in the epidemiology of smallpox.

In a number of outbreaks in western nations, as well as in many instances in endemic countries, itinerant individuals of various sorts have been shown to be responsible for the spread of disease from one area to another. In Africa, many types of mobility are frequent: traditional nomadism, systematic seasonal migration by larger or smaller population units, wideranging traders, individual movement from rural to urban areas and back again

in search of work, and the ebb and flow of yillage people for social and marketing purposes. The relative importance of these types of movement in initiating and sustaining outbreaks must be determined.

9. The role of hospitals as a source of smallpox transmission.

In most outbreaks in western nations in the last two decades, hospitals have performed a singularly sinister role in perpetuation of smallpox following the hospitalization of cases. While perhaps of lesser relative importance in West Africa than in the western world, the role of the hospital in perpetuation of the disease needs to be carefully documented.

10. The relative importance of age cohort in the transmission of smallpox.

Age as a determinant in the maintenance of smallpox transmission has been only vaguely referred to in the past. Yet there are suggestions in Indian outbreaks that unvaccinated children may be more important as transmittors than are unvaccinated adults (and more certainly than are vaccinated adults). The implications of this phenomenon, if true, for a mass vaccination program are obvious. Data bearing on this question may be collected by study of secondary attack rates in households in relation to age of the first case. Less directly, but perhaps just as usefully, age specific epidemic curves should be constructed for extensive outbreaks in order to determine whether one age cohort or another may be involved relatively earlier during the course of an outbreak.

11. Vaccination coverage necessary to interrupt transmission.

Due to local factors, the response to the mass vaccination campaign is likely to result in variable proportions of coverage in different communities. Much of the theory of smallpox eradication and measles control is based on the assumption that a certain level of coverage, frequently stated to be 80 percent, is adequate to result in interruption of smallpox transmission. This figure is not based on any particularly valid data and presumably would vary according to the characteristics of the population approached. Although

an analysis of this sort will require imagination, and the assessment of transmission in a moderately large number of communities for which coverage data are available, it should be possible to ascertain minimum levels necessary for interruption of transmission according to community size. Such factors as the in-flow of susceptibles by migration, the level of the birth-rate, and indices of crowding will have to be taken into consideration to make such an analysis meaningful. This problem is obviously the most difficult of those enumerated to resolve adequately. However, it is also singularly key to the ultimate success of the mass campaign.

12. Complications of measles, smallpox, other exanthems and smallpox vaccination.

Except for measles, and that incompletely, little information apart from anecdote or hospital records is available regarding complications of these exanthems in Africa. Quantitative assessments of these complications in "natural" communities, as distinct from hospitalized populations, would be most valuable.

C. Investigations Requiring Laboratory Assistance.

Since laboratory studies are time-consuming and complex, and since experience has shown that an active epidemiologist can readily swamp a laboratory of virtually any size, it is incumbent that study plans involving any significant number of laboratory studies be submitted for discussion with the RPO and Atlanta Headquarters.

 Smallpox virus types (variola major, intermediata and minor) present in West Africa.

As alluded to in Section A.4, little is known of the laboratory characteristics of smallpox viruses in West Africa. By characterizing viruses from patients in many smallpox outbreaks, and correlating these findings with the case fatality ratios and the severity of non-fatal disease in these epidemics, an epidemiologic map of smallpox can be developed which describes the distribution of each virus type in West Africa.

2. Possible relationship of simian pox virus diseases to those of man.

It is generally accepted that man is the only natural host of smallpox virus. It is partially on this premise that the prospects for smallpox eradication are considered to be so optimistic. Experimentally, monkeys can be infected with variola virus by exposure to aerosols containing the virus. The disease course in monkeys is comparable to that in man. Viremia occurs, with vesicular and pustular lesions. In the experimental situation, disease is mild and death rare (Hahon⁴).

In nature, smallpox in monkeys has been reported several times but virologic confirmation is lacking as virus culture techniques had not been developed at the time of these observations (Schmidt⁵, Bleyer⁶, Councilman⁷). During an epidemic of human smallpox in Indonesia in 1949, smallpox was reported in an orangutan in a zoo (Bras⁸).

While the natural occurrence of variola in monkeys, and its potential transmissibility to man, is extremely doubtful, the possibility that monkeys might serve as reservoirs for smallpox virus cannot be completely discounted. Wherever human smallpox occurs in West Africa in association with monkey populations, animals should be obtained for examination and specimens collected for virologic and serologic studies to confirm or disprove the notion of "jungle smallpox."

3. Neutralizing antibody response following vaccination.

Only limited data are yet available regarding comparative neutralizing antibody responses among primary vaccinees and revaccinees in different age groups. Age groups of particular interest are infants less than 6 months of age, children, adults about 20 - 40 years old and adults over 40 years of age.

Studies now in progress in Tonga should provide a number of answers to questions in this area. Because it is difficult in Africa to obtain adequate numbers of persons, particularly in the older age groups, who have neither

been vaccinated previously nor have experienced smallpox, only a few highly selected studies of this type can be contemplated in Africa.

4. Correlation of smallpox antibody levels with protection against disease.

The relative role of humoral antibodies in conferring protection against smallpox has not been defined although it is generally agreed, on theoretical grounds, that levels of serum neutralizing antibody should correlate to some degree with the level of protection. The observation that hyperimmune globulin confers some protection when administered to contacts following exposure is further suggestive evidence (Kempe⁹).

Reasonably definitive answers to this question might be obtained by taking blood specimens from household contacts of smallpox cases. By careful follow-up of these contacts to determine which did and which did not develop smallpox and correlation of this information with the neutralization titers obtained, more definite answers regarding protective titer levels should be forthcoming. However, since vaccination of household contacts at the time of recognition of a case is customary practice and since vaccination itself induces increased neutralizing antibody levels, this type of study will require collection of detailed epidemiological data and, undoubtedly, several blood specimens to permit interpolation of the results. Since this study is of major importance to the entire eradication program, it is hoped that a cooperative study employing a common protocol can be developed in several areas. Further details will be sent to you.

D. Multiple Antigen Administration.

The economy involved in being able to administer, with safety and efficacy, several antigens simultaneously is self-evident. This is of particular importance in African countries in which funds are limited and trained medical and paramedical personnel in short supply.

From available data, there is reason to believe that a number of antigens (DPT (diphtheria-pertussis-tetanus), typhoid, poliomyelitis, measles, smallpox, yellow fever and BCG vaccines) might be administered simultaneously with acceptable results from the standpoint of both safety and efficacy. Careful field evaluation and appraisal is required, however, before this can be done.

Of immediate importance to the African program are measles, smallpox, yellow fever and BCG vaccines. As described in the earlier section dealing with measles vaccine and as summarized by Karzon and Henderson¹⁰ and in the WHO Report on Virus Vaccines¹¹, there are reasonable data demonstrating the safety and efficacy of simultaneous administration of measles/smallpox, smallpox/BCG and yellow fever/smallpox vaccines. Definitive field evaluations are required for other combinations. Such studies will require careful serological appraisal of vaccinees and close follow-up for frequency of febrile responses and other untoward reactions in progressively larger numbers of vaccinees. If the opportunity occurs to conduct such studies, the study designs and protocol should be discussed with RPO and Atlanta Headquarters staffs.

E. Efficacy of Antiviral Compounds in the Prophylaxis of Smallpox.

Compounds of the thiosemicarbazone group have been demonstrated to have anti-viral activity against pox viruses both in-vitro and in-vivo. Studies in man indicate that this family of compounds has no effect in the treatment of established smallpox disease (Rao, et al, 1966¹²) but that these agents seem to have a prophylactic effect when given early in the incubation period (Bauer, et al, 1963¹³; Rao, et al, 1966¹²). A good double-blind study remains to be done to settle the question of the prophylactic efficacy of the thiosemicarbazone compounds in decreasing smallpox morbidity and mortality as compared to simple vaccination.

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ADMINISTRATIVE SUPPORT

Administrative support in each assignment area will be provided by the Communicable Disease Center, the Embassy, the AID Mission, or combined Administrative and Management Operation (CAMO). In some instances more than one of these administrative support resources will be used. The AID Executive Officer (AID Representative) or his designee will be your local point of contact for obtaining administrative services.

Unfortunately, there are, at present, no guidelines, or step-by-step procedures which would enable you to reach a solution to your administrative problems. We have, however, prepared guides which separately contain basic information on leave, travel, allowances, supply and inventory which you will find helpful.

As you encounter and resolve the principal administrative problems in your respective areas, you should let the Regional Project Office know just how you developed the workable solution. This information can then be disseminated throughout the project area to assist others who face similar situations. In addition, your comments will contribute to a base of vital information from which a manual of administrative procedures can be developed. Personnel entering the Smallpox Eradication Program at a later date can then profit by your experiences and groundwork.

There is no doubt that when you first report to your post you will encounter a myriad of perplexing administrative problems. Solutions to these problems will depend largely on your own imaginative approach to them.

I. ANNUAL LEAVE

A. Accrual

Commissioned Corps

- Annual leave is accrued at the rate of one day for each 12 consecutive days of active duty and leave credits are based on the calendar year.
- You may carry forward 60 days of unused leave from one year to another.
 Leave in excess of 60 days not used by December 31 is forfeited.

Civil Service

- Annual leave is accrued at a rate which depends on the length of your creditable combined civilian and military service.
 - a. Less than 3 years credited service entitles you to 4 hours per pay period. (There are 26 two-week pay periods in each leave year.)
 - b. Three to fourteen years entitles you to 6 hours per pay period.
 - c. Fifteen years or more entitles you to 8 hours per pay period.
- 2. As an employee in an overseas area, you may accumulate a maximum of 45 days, instead of the normal 30 days maximum to be carried over from one leave year to the next. When you return to the United States, the 45-day maximum will still apply. This 15-day excess will remain to your credit until you use annual leave in a leave year in excess of the amount earned in that year. Your balance at the end of that leave year will then be your new maximum accumulation. When the balance drops below 30 days, the maximum accumulation permitted for future years will again be 30 days.

B. Use of Leave

As far as practicable, and when the interest of our program is clearly protected, annual leave will be granted for the period you request.

Commissioned Corps

An application for annual leave should be requested in writing, using
 PHS Form 1345, obtainable from RPO, and submitted to the Regional Project

Office. This should be done as soon as you decide when you want to take leave so that leave can be approved, in advance. If it is not possible for you to do this because of an emergency you should notify the Regional Office as soon as possible and submit PHS Form 1345 when you return.

- 2. Annual leave is granted in full days. Absence for less than a full work day is considered station leave and is not chargeable to annual leave. The date and amount of station leave should be submitted to the Regional Project Office.
- 3. Non-work days at the beginning, or end, of a period of annual leave are not chargeable against your leave account. Non-workdays that fall within a period of leave are chargeable to annual leave. This includes legal holidays. A consecutive period of absence from duty may not be authorized in two or more parts to avoid charging the non-workdays falling within the period of annual leave.

e.g.,

Leave is charged for 2 days.

Leave is charged for 6 days.

Civil Service

 You should apply in advance for approval of anticipated leave. Submit "Application for Leave," SF-71, obtainable from RPO, to the Regional Project Office as soon as you have decided when you want to take leave.

- 2. When you must be absent because of an unforeseen reason, you must notify the Regional Project Office as soon as possible after your return to duty. Submit SF-71 at this time so that the proper charge to your annual or sick leave account can be made.
- 3. The minimum leave charge is one hour. Charges for more than one hour and less than one day are made in multiples of one hour.

C. Leave Advance

Annual leave can be advanced in emergency situations to both Commissioned Corps and Civil Service personnel. If you find it necessary to request leave which you have not earned, submit a request containing the particular circumstances to the Regional Project Office.

II. SICK LEAVE

A. Accrual

Commissioned Corps

1. There is no accrual, or charge of sick leave.

Civil Service

- 1. You earn one-half day of sick leave for each full bi-weekly pay period.
- 2. Sick leave is available for use at any time during the pay period in which it is earned or at a future date.
- Unused hours of earned sick leave are carried over from pay period to pay period and year to year. There is no limit on such accumulation.

B. Use of Sick Leave

Commissioned Corps

- 1. Sick leave is granted as needed when you are ill.
- When you are absent because of illness of one of your family, your absence is charged to annual leave.
- 3. When you are unable to report for duty because of personal illness, you must notify the Regional Project Office. When you return to duty you should submit Form PHS-1345 to the Regional Project Office.

Civil Service

- 1. Sick leave should be used:
 - a. When you are incapacitated for duty by illness or injury.
 - b. For your medical, dental, or optical examination or treatment.(To be requested in advance.)
 - c. When your care is required for a member of your immediate family who is sick with a disease for which local health authorities prescribe quarantine, isolation, or restriction of movements for a specified period (e.g. chickenpox, infectious hepatitis, measles, mumps, scarlet fever, streptococcal sore throat, whooping cough).
- Sick leave <u>cannot be</u> used to take care of a member of your family who
 does not have a serious contagious disease such as listed above.

C. Advance of Sick Leave

Commissioned Corps

1. Not necessary since sick leave is granted as needed when you are ill.

Civil Service

- 1. Sick leave up to 30 days may be advanced in case of serious disability or ailment and when required by the exigencies of the situation.
- 2. The request for advanced sick leave must be supported by a medical certificate.

D. Evidence to Support Sick Leave

Commissioned Corps

- If you are sick for more than 3 days, you must record the following information in the "Remarks" section of Form PHS-1345.
 - a. The nature of the illness or disability or
 - b. The need for medical services.
- You may be required to submit a medical certificate signed by the attending physician, or other acceptable evidence.

3. The medical certificate, when you have been absent because of a contagious disease, must indicate that you are not a hazard to yourself or others.

Civil Service

A medical certificate or other acceptable evidence is required for a grant of sick leave of more than 3 work days. It may also be required for shorter periods.

III. HOME LEAVE

Commissioned Corps

- A. When you have completed your tour of duty, travel may be authorized for you and your family for the purpose of taking home leave in the United States, if it is contemplated that you will return overseas immediately following the period of leave.
- B. The minimum grant of home leave will normally be 20 days and the maximum normally 45 days. Home leave is chargeable to your annual leave account.
- C. Travel for home leave is limited to the direct distance between your overseas post and the place where you were last stationed in the United States. Any travel in excess of this distance will be at your own expense.

Civil Service

- A. You may be granted home leave at the end of your tour of duty.
- B. The minimum grant of home leave taken in one continuous period will normally be 20 workdays. The maximum will normally be 45 days in any combination of home and annual leave.

TRAVEL VOUCHER GUIDE

These instructions are designed to assist you in the preparation of your travel voucher which you must submit for reimbursement of travel and other expenses.

A. Administrative Approval of Vouchers

- At present, the AID Mission Director, AID Representative, or his designee is responsible for approving the voucher for your travel and other related expenses. These expenses include:
 - a. Authorized travel within your assigned country and in other foreign countries.
 - b. Any medical travel for you and your dependents.
 - c. Travel for rest and recuperation.
 - d. Emergency expenditures.
 - e. Official local transportation.
 - f. Other authorized expenses.
- 2. Each Medical Officer will recommend for approval the travel voucher submitted by the Operations Officer(s) in his assigned area(s) by placing his signature in the space opposite the words "Recommended for Approval" if he is satisfied the travel was made and the related duties performed by the individual(s).
 - 3. The authorized certifying officer at the AID Mission may also require, prior to his certification, that the voucher of the Medical Officer be submitted to a responsible official who has requisite knowledge of the travel.

B. Submission of Vouchers

1. You are responsible for the preparation and submission of your travel voucher. In order that you may be reimbursed promptly and accurately, you should keep a diary of dates and hours of departures and arrivals, reimbursable expenses incurred, rates of exchange involved and any other information which prove helpful in the preparation of your voucher.

- You will submit your voucher for reimbursement of expenses once each month
 in accordance with local procedure established by the Mission Director or
 his representative.
- 3. At the option of the local Mission, you will use either the SF-1012, Travel Voucher, or Form FS-286, Foreign Service Travel Voucher. Travel Vouchers should be typewritten or printed in ink, and submitted in quadruplicate to the appropriate administrative official at the AID Mission.

C. Supporting Documents

- Your voucher must be accompanied, when applicable, by the following supporting documents:
 - a. Receipts. These are generally required and should always be obtained when practicable.
 - b. A copy of the <u>Commercial Bill of Lading</u> when you have paid for any authorized shipment of effects or articles.
 - c. Written approval by the authorizing officer for expenses incurred without prior authorization.
 - d. Evidence such as the stub of the excess baggage coupon (in the case of air travel) or a carrier's receipt (surface travel) when you have paid authorized excess baggage charges.

D. Required Information

- 1. In addition to normally requested information you must furnish the following, where appropriate:
 - a. The number and date of the travel authorization.
 - b. The serial number of the transportation request, points of origin and destination, name of carrier, and the value of the ticket, if possible.
 - c. The name and location of the disbursing officer and his voucher number when a ticket is purchased by him for you.
 - d. A comparative statement of the cost of actual and allowable travel and transportation, whenever a question of comparative cost is involved

When normal methods or schedules are not used for personal convenience of traveler.

- e. On any voucher for the travel of dependents, the names and relationships of the dependents and the date of birth of each dependent child.
- f. The net weight of effects when the shipment expense of these effects has been paid by you and you claim reimbursement on your voucher.
- g. When international borders or boundaries dividing areas with different per diem rates are crossed via surface transport, the exact crossing time must be entered.

E. Disposition of Unused Tickets

- If you have unused tickets to turn in, or if the transportation furnished you was of lesser value or different character than that originally requested, unused tickets should be attached to your vouchers and the following information included in the voucher as appropriate.
 - a. Ticket number and serial number of the transportation request against which the ticket was issued.
 - b. Name of the carrier to whom the transportation request was issued.
 - c. The points between which the ticket was not used or an explanation of the difference in the transportation which was actually furnished and that which was originally requested.
 - d. If the ticket was purchased at an AID Mission without use of a transportation request, the name of the Mission, the disbursing officer's voucher number, and the period of account in which the original ticket was obtained, if available. Otherwise indicate the date of purchase.
 - e. Reason for non-use of ticket or variation in transportation furnished.

F. Miscellaneous Information

1. Reimbursable Expenses

a. Per Diem

This allowance is authorized to cover the increase in your living expenses while in a travel status (e.g. meals, lodgings, tips, fees, telegrams and telephone calls, and incidental personal expenses.)

Per Diem is computed by multiplying the number of days by the per diem rate by the number of travelers. (Any dependent child under 11 years of age is entitled to one-half of the maximum per diem rate. The calendar day is divided into four quarters, as follows:

From 12:01 a.m. to 6:00 a.m.

From 6:01 a.m. to 12:00 p.m.

From 12:01 p.m. to 6:00 p.m.

From 6:01 p.m. to midnight.

Per diem rates vary within countries (Cities - Bush) and between countries. Listed on the following page are maximum per diem rates by country. Mission directors may designate lower per diem rates for certain areas within their respective countries.

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1.	Cameroon	\$26
2.	Central African Republic	28
3.	Chad	28
4.	Dahomey Salar Dahomey Salar Dahomey Salar Dahomey	25
5.	Gabon	25
6.	Ghana	
	Accra	24
	Other	20
7.	Guinea	23

Cou	mtry with the second of the se	Amount
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	Abidjan	\$26
	Other one investment of the properties of the	18
9.	Mali To whole to enelg mort soul desixed true	32
10.	Mauritania	24
11.	Niger Delivoreness sa baceblo essou driv quite	24
12.	Nigeria (Francisco de Casto do entre tot ton) rest	22
13.	Senegal	28
14.	Sierra Leone	23
15.	Togo	20
16.	Upper Volta	24

When change in per diem rate is made, the rate of per diem in effect at the beginning of the quarter in which the change occurs shall continue to the end of such quarter.

For continuous travel of more than 24 hours, the beginning hour of a per diem quarter in which a departure time falls is used as the hour from which to compute per diem. (For example: If you leave headquarters at 7:00 a.m., the per diem computation begins at 6:01 a.m.)

The closing hour of a per diem quarter in which an arrival time falls is used as the hour through which per diem is computed. (For example: If you arrive at your home city at 4:15 p.m., the per diem computation closes at 6:00 p.m.)

Briefly, then, you may claim 1/4 of the specified daily rate for each 6-hour period or fraction thereof that you are away from your headquarters on the day you begin or end travel and the full daily rate for each full day you are in a travel status.

b. Transportation Expenses

Transportation expenses include all necessary official travel on railroads, airlines, and other usual means of conveyance, including the usual taxicab fares from place of abode or place of business; expenses of official telegraph, telephone, radio and cable messages in connection with items classed as transportation; airport tax; baggage transfer (not for tips or fees to porters). Charges for transfer of baggage must be supported by a statement of the number of pieces involved and the necessity for the transfer of hand baggage must be explained. You should explain in detail the official necessity for incurring any unusual or extraordinary expenses for which reimbursement is claimed.

c. Fees

Fees in connection with the issuance of passports, visas, costs of photographs for passports and visas, birth, health, and identity certificates, and of affidavits, and charges for inoculations which cannot be obtained through free approved dispensaries.

d. Currency Charges

Reimbursement will be made for commissions for conversion of currency, and charges covering exchange fees for cashing any United States Government checks or drafts issued in reimbursement of traveling expenses.

e. Miscellaneous

Other necessary expenses for conduct of official business may be reimbursed.

2. Non-Reimbursable Expenses

- a. You must pay for the items listed below from your per diem allowance:
 - (1) Meals and lodgings; radios or television in rooms; fans, bath.
 - (2) Fees and tips to waiters, porters, baggagement, bellhops, etc.
 - (3) Laundry; cleaning and pressing.

- (4) Telephone and telegraph messages reserving hotel accommodations, requesting leave.
- (5) Accommodations other than "less than first class" when obtained for personal convenience.
- (6) Excess baggage unless authorized or approved.

G. Voucher Checklist

You should observe the following before submitting your voucher.

- 1. Give your voucher a final close check.
- 2. Sign and date the original.
- 3. Attach all receipts and unused tickets securely to the voucher.
- 4. Number receipts consecutively.
- 5. Initial any erasures and alterations in totals on your voucher.
- Make certain that all dates and hours of departures and arrivals, modes of transportation and explanation of any stop-overs have been furnished.

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ACCOUNTING CLASSIFICATION (Appropriation symbol must be shown; other classification optional)

^{*} Abbreviations for Pullman accommodations: MR, master room; DR, drawing room; CP, compartment; BR, bedroom; DSR, duplex single room; RM, roomette DRM, duplex roomette; SOS, single occupancy section; LB, lower berth; UB, upper berth; LB-UB, lower and upper berth; S, seat.

** FRAUDULENT CLAIM—Falsification of an item in an expense account works a forfeiture of the claim (28 U.S.C. 2514) and may result in a fine of not more than \$10,000 or imprisonment for not more than 5 years or both (18 U.S.C. 287; id. 1001).

SCHEDULE OF EXPENSES AND AMOUNTS CLAIMED

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* Abbreviations for Pullman accommodations: MR, master room; DR, drawing room; CP, compartment; BR, bedroom; DSR, duplex single room; RM. roometi DRM, duplex roometic; SOS, single occupancy section; LB, lower berth; UB, upper berth; LB-UB, lower and upper berth; S, seat.

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SCHEDULE OF EXPENSES AND AMOUNTS CLAIMED

PREVIOUS TEMPORARY DUTY (Complete these blocks only if in travel status immediately prior to period covered by this voucher and if administratively required) DEPARTURE FROM OFFICIAL STATION TEMPORARY DUTY STATION LAST DAY OF PRECEDING VOUCHER PER' (DATE) (HOUR) (DATE OF ARRIVAL) AUTHORIZED MILEAGE RATE ______¢ DATE AMOUNT CLAIMED NATURE OF EXPENSE 19_65 SPEEDOMETER READINGS MILEAGE SUBSISTENCE OTHER Voucher includes claim for expenses of Martha Drake, wife; and Helen Drake, daughter, DOB 6/13/56. Rate of exchange: 640 Italian Lira = \$1.00 Aug. 1 LV Nocity 11:54 a.m. 5:55 p.m. ARR Milan Traveled in automobile driven by Albert Price, US AID/Graustark - no charge LV Milan 6:20 p.m. 10:25 p.m. ARR Genoa Baggage and 2 trunks to shipside - 3200 lira 5 00 Overnight in hotel across from station 2 Taxi hotel to shipside - 640 lira 1 00 LV Genoa - SS Independence 1:00 p.m. 3 steamer chairs, cushions, & rugs (receipt attached) 15 75 13 ARR New York 9:00 a.m. Ship delayed due to storm at sea. Taxi dock to LaGuardia Field - 3 pieces 6 00 baggage Coinbox telephone call to Washington -6 minutes official - O/EUR - Walter Sain 1 15 Mr. Drake: 1:30 р.т. 13 LV New York via Air ARR Washington, D.C. 2:40 p.m. Taxi to hotel plus tip 1 75 14-20 Consultation in AID/W 9:00 a.m. 21 LV Washington via p.o.a. 6:00 р.т. ARR Pittsburgh Speedometer reading - start 526; finish 894 368 miles @ 12c = \$44.1620 Travel could have been performed: 8:50 p.m. LV Washington via PRR ARR Pittsburgh 5:12 a.m. \$ 5.00 Lower Berth 1st Class Rail 13.44 Grand total to face of voucher (Subtotals, to be carried forward if necessary)

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TRAVEL YOUCHER-COMMINION SHELL SCHEDULE OF EXPENSES AND AMOUNTS CLAIMED

John Drake Pavee's Name AUTHORIZED MILEAGE RATE DATE AMOUNT CLAIMED NATURE OF EXPENSE 65 SPEEDOMETER NO. OF READINGS MILES 19_ SUBSISTENCE OTHER MILEAGE 30 Brought forward 65 Per diem and transportation claimed in accordance with more economical method 18 44 of travel Mrs. Drake and Daughter: 1:45 p.m. Aug. 13 LV New York - via air - TWA 3:50 p.m. ARR Pittsburgh 20 Taxi and 2 pieces of baggage to residence and tip Per Diem: Mr. Drake, wife & daughter: 3/4 day @ \$16.00 X 21/5 30 00 Genoa Aug.1 135 00 10 00 9 days @ \$6.00 X 21/2 Sailing 2-10 Sailing 11-12 2 days @ \$2.00 x 21/2 Mr. Drake: 16 00 U.S. 13 1 day @ \$16.00 112 00 Consultation 7 days @ \$16.00 14-20 4 00 U.S. 1/4 day @ \$16.00 21 Mrs. Drake & Daughter 18 00 U.S. 13 3/4 day @ \$16.00 x 1½ Charges by Railway Express for 2 trunks and 3 pieces of baggage. New York dockside to residence in Pittsburgh - 425# Gross 43 25 weight (receipt attached) 1 30 Tax Standard Form No. 1012b 7 GAO 5300 Grand total to face of voucher 76 40 18 44 325 00 \$419.84 (Subtotals, to be carried forward if necessary)

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TRAVEL VOUCHER—CONTINUATION SHEET SCHEDULE OF EXPENSES AND AMOUNTS CLAIMED

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ALLOWANCE BENEFITS

As a United States citizen employee of the Government stationed in a foreign country, you are eligible to receive certain allowances and other payments.

The following information concerning allowance benefits is intended solely as general information which you may find helpful. This guide is not to be used as a substitute for the official regulations concerning allowances.

Allowances become payable as of the date you arrive at your post. Immediately following your arrival you should submit to the administrative officer the post application forms (furnished by the post) for the allowances for which you are eligible.

Unfortunately there are no exceptions to the regulations to take care of worthy individual cases of unforeseen financial hardships. You do, however, continue to receive allowances for which you are eligible while in a travel basis drawing per diem.

When your basic salary is increased, generally the amount of your allowances also increases. Allowances are not subject to retirement deduction and except for the post differential - not taxable.

Your post differential is always paid as part of your regular salary check.

Your other allowances will probably be paid in local currency, but this depends on conditions at the post and the disbursing regulations of the post.

A. Post Differential

This allowance is additional compensation paid to you for working in a
foreign area where unusual hardship exists. A post differential of 10, 15,
20, or 25 percent of your base salary is paid depending on the degree of
hardship. Below are listed the percentage amounts of post differential
paid for the assignment areas (as of July 1966).

Country	Post Differential Rate	Country Pos	t Differential Rate
Cameroon	25%	Mauritania	25%
Yaounde	15%	Nouakchott	20%
C.A.R.	25%	Niger	25%
Chad	25%	Nigeria	25%
Dahomey	25%	Enugu	20%
Gabon	25%	Ibadan	20%
Ghana	25%	Kaduna	15%
Accra	15%	Lagos	15%
Guinea	25%	Senegal	15%
Ivory Coast	20%	Dakar	10%
Abidjan	15%	Sierra Leone	25%
Liberia	25%	Togo	25%
Mali	25%	Upper Volta	25%

- 2. Each post has been rated based on criteria of extraordinarily difficult environmental conditions. Ratings are reviewed periodically and are subject to change. Some of the factors involved in determining the post rating are: geographic isolation, inadequate or substandard housing, lack of recreational facilities, lack of consumer services, adverse climate, incidence of disease, lack of health control measures, and inadequate medical and hospital facilities.
- Your post differential is paid with your salary check and is subject to income tax.

B. Post Allowance

- This is a "cost-of-living" allowance paid to employees assigned to a high-cost foreign post. It is primarily a balancing factor to keep your salary worth what it would be in Washington, D.C.
- 2. The amount of your post allowance is determined by living costs at your post, your salary, and family status. Posts are grouped in 15 classes, each representing a percentage increase over the cost of living in Washington, D.C., and each of you also fall into one of 38 groups according to your salary and family status. (A table of post allowances may be found in the Standardized Regulations for Government Civilians in Foreign Areas.)

An additional allowance is paid for each of your children according to the following table:

Country	Annual Rate per Child	Country Ar	nnual Rate per Child
Cameroon	\$100.00	Mali	\$100.00
C.A.R.	\$110.00	Mauritania	100.00
Chad	110.00	Niger	90.00
Dahomey	85.00	Nigeria	75.00
Gabon	100.00	Senegal	90.00
Ghana	70.00	Sierra Leone	75.00
Guinea	90.00	Togo	85.00
Ivory Coast	85.00	Upper Volta	90.00
Liberia	85.00	AND STREET, BUSINESS	

C. Temporary Lodging

- 1. This allowance is to reimburse you for hotel room costs for you and your family if you arrive at your post and permanent quarters or suitable temporary quarters are not immediately available.
- 2. The allowance is paid from the date you arrive until you occupy your permanent or suitable temporary quarters, or for 3 months, whichever is less.
- 3. The allowance amount varies from post to post depending on costs at the post.

 The temporary lodging allowance is based on <u>actual expenditures</u> which must not exceed the applicable maximum rates. Maximum rates are established for you and for each member of your family 11 years of age or older. For each child less than 11 years, the maximum rate is one-half.
- 4. The allowance is intended to cover the cost of a single room and bath, including taxes, heat, light, fuel, water, and any other service charges which you are required to pay. The rates of hotels ordinarily used by Government employees at the post and your own daily hotel expenditures which you report are the basis for determining the amount of allowance paid.
- 5. The temporary lodging allowance is intended to cover room rent only. The cost of meals is not included in the temporary lodging allowance even if the meals are included in the hotel rate (see also "Supplementary Post Allowance" below). When room and meal rates are combined, the allowance is limited to 60 percent of the combined rate, or the maximum temporary lodging allowance rate, whichever is lower.

- 6. You are entitled to all other allowances while you are drawing a temporary lodging allowance except for a living quarters allowance and travel per diem. If you are required to undertake official temporary duty travel while occupying temporary quarters, you may draw the temporary lodging allowance if you must continue to pay expenses for the temporary lodging while you are away.
- 7. Temporary lodging allowance is also authorized when you are required to vacate your permanent quarters just prior to final departure from your post. The allowance is then paid for a maximum of one month.
- 8. The temporary lodging allowance is paid bi-weekly.

D. Supplementary Post Allowance

- 1. This payment is a fixed daily rate ranging up to \$6.00 for which you may be eligible if you have 2 or more dependents and are occupying temporary non-housekeeping quarters upon first arrival at your post. It is designed to help defray the high cost of hotel or restaurant meals.
- 2. You may be eligible for this supplementary post allowance even if you are not drawing a temporary lodging allowance since you may be furnished temporary quarters but without facilities for preparing family meals.
- 3. The allowance may be paid from the date you and your family occupy temporary nonhousekeeping quarters and can be paid up to 3 months or until you are assigned housekeeping quarters, whichever is sooner.
- 4. You may receive all other allowances to which you are entitled while drawing a supplementary post allowance.
- 5. The supplementary post allowance is paid bi-weekly.

E. Education Allowance

 This allowance is paid to assist you in providing education for your children who are in grades 1-12. Education costs for which the allowance is paid generally include tuition, books, supplies, necessary transportation, and board and room if there is no adequate school at the post.

- 2. Education allowances are not paid at some post% because the schools are adequate (i.e., providing curriculum and teaching reasonably comparable to public schools in the United States) and free or of relatively low cost.

 Education costs must exceed approximately \$50.00 per child per school year before an education allowance is established at the post.
- 3. There are two education allowance rates.
- a. "School-at-post" rate. This rate is established based on the costs of a local adequate school.
- b. "School-away-from-post" rate. This allowance rate is established where a local school is inadequate. It is to assist in defraying the cost of sending your child to the nearest and least expensive adequate boarding school.

If you elect to send your child away to school, despite the availability of an adequate local school, you are permitted the equivalent of the allowance available for the post school.

- 4. The education allowance may include, under certain conditions, supplementary instruction costs for foreign language and some other subjects. Music lessons, dance lessions, riding lessons, etc., are not included.
- 5. Remember! You are not required to send your child to the school on which the allowance is based in order to get the allowance. You can send your child to any school including one in the United States. If the allowance is based on an available U.S. Government-operated or sponsored school, you are not eligible for an allowance should you send your child to school away from your post. If your child is living in the United States with a legal guardian, or if a separate maintenance allowance has been granted, you are, again, not entitled to an education allowance. Likewise, if you send your child to the United States under the separate Educational Travel Benefit, you cannot draw the education allowance.

6. As soon as you arrive at your post, you should complete the necessary application form in order to draw the education allowance. This form will be provided to you.

F. Educational Travel

- 1. After your child has lived outside of the United States for 45 consecutive days he is entitled to one round trip to the United States to gain a high school education, and is entitlted to another round trip for his college education. If you take advantage of this benefit you cannot draw the education allowance.
- At the college level, educational travel is the only education benefit.
 Moreover, the last trip to the United States must begin before your child is
 21 years of age except for the following:
 - a. Age 23, if he is finishing his senior year of college.
 - b. Older age if his college education was interrupted by military service.
- 3. In order for you to qualify for the educational travel benefit, your child must be enrolled full time at the undergraduate level offering academic courses leading to a degree.
- 4. Travel expenses normally include air transportation at lowest rate, travel per diem, and transfer of a specified amount of baggage which is determined by the post.

G. Travel Per Diem

- 1. This allowance is designed to cover general subsistence expenses when you are traveling on official business.
- 2. The maximum basic rates for travel in foreign areas varies from country to country and sometimes within countries. The rates are set up by the Department of State after considering the local costs for hotel room, meals, tips, and incidental expenses. Per diem rates are listed in your <u>Travel Voucher Guide</u>.

H. Foreign Transfer Allowance

- This allowance is only a token payment, but is provided to you to help offset some of the expenses you have incurred in moving from one climatic zone in the United States (Zone 2) to another climatic zone in Africa (Zone 3).
- 2. Your post is grouped with others into one of three zones according to climate.
 You are also placed in one of three groups according to your family size.
 The foreign transfer allowance is then paid according to the following table:

a. Employee without family:

\$75.00

b. Employee and one member:

\$125.00

c. Employee and more than one member of family:

\$175.00.

 The foreign transfer allowance is paid in a lump sum payment following your arrival at your post.

SUGGESTED OPERATIONS FOR STORAGE AND MAINTENANCE OF PARTS INVENTORY

In the West African countries which will be participating in the Smallpox Eradication Program, it will be necessary to have adequate storage facilities for all reserve vehicles, jet injectors, spare parts and miscellaneous field equipment. It is expected that each country will provide suitable storage areas which may be located in existing government warehouses. In the event that some countries do not provide the necessary facilities for storage, it will be the responsibility of the Operations Officer to expedite procedures which would provide for these facilities. This will have to be accomplished by working with the office of the Minister of Health in the country.

The following suggestions may prove useful to the Operations Officer in establishing adequate storage facilities and procedures for the operation and maintenance of parts inventory.

Storage

The storage area should be locked when not in use and close supervision of personnel assigned to the area should be maintained at all times. Pilferage and misplacement of parts will seriously handicap the success of the country's Smallpox Eradication Program.

If adequate storage cabinets are not available in the respective countries, it may be necessary to have them constructed locally. It is suggested that cabinets with shelves be used rather than bins due to various sizes of the different parts.

The dimensions of each cabinet should be: height 7-1/2 feet, width 4 feet, depth 1-1/2 feet (see attached Figure 1). The cabinets should be constructed with 3/4-inch lumber with the backs made of 1/2-inch plywood. Four of these cabinets should be sufficient to house six sets of truck spare parts with the exception of the engine which may require a separate storage container. An additional two cabinets can be used to store the jet injector and miscellaneous equipment parts.

The cabinets should be placed side by side and may be fastened together for greater stability. The cabinets may also be fastened to the wall to keep them from falling forward in the event that someone pulls or climbs on the front side.

Each cabinet should have six rows of shelves, each of which should be identified with a letter (i.e. top shelf "A", second shelf "B", bottom shelf "F"). Two storage spaces should be allotted to each cabinet shelf. For example, the first cabinet will have spaces numbered "1" and "2" for all six shelves; the second cabinet will have spaces "3" and "4", the third cabinet "5" and "6", and the fourth cabinet "7" and "8". No dividers should be used between the spaces within the individual cabinets. (See attached Figure 1).

One of the methods that could be used for storing outboard motors is shown on the attached illustrations. (Figure 2).

The truck parts should be placed on the shelves as they are listed on the Quarterly Inventory Report starting with the alternator, part number 3000010, which will be stored on shelf "A" in space #1. Space #1 will also be used to store other parts until the space is filled up, but not overcrowded. Continue to store parts in spaces 2, 3, 4, etc., then proceed to shelf "B".

Inventory

The spare parts for equipment will arrive probably packed in waterproof material as well as the part itself dipped in cosmoline. An IBM card may be already attached to the outside of the part showing the part number and the description. For the purpose of performing the "Quarterly Inventory Report" this card should remain attached to the part until the part has been issued. As the various parts are used the IBM card should be returned to the Operations Officer with the Vehicle Breakdown Report.

The storage location of each part should be printed on the Kardex inventory cards that have been furnished to each country and/or region.

If possible, all parts should be kept in their water tight coverings until a part is actually issued. This is especially important in the areas of high humidity.

Every truck will have some spart parts which will be kept in the storage box on the truck. These parts should be considered as issued and used on the Quarterly Inventory Report.

It will be necessary to establish reorder points on all parts as soon as possible. It is suggested that for the first six months the Operations Officer should very diligently observe the amount of time that parts are being used so that more realistic reorder points can be ascertained. Reorder points can, at first, be arbitrarily assigned to each part and changed at a later date if it is desirable to do so. The amount of delivery time required to obtain reorder parts will indicate what a part reorder point should be to insure an adequate supply of parts on hand.

DAILY, WEEKLY, MONTHLY MISCELLANEOUS EQUIPMENT CHECKLIST

Daily	Weekly	Monthly
Camping Equipment Tool Box/Tools Refrigerator Motor Bike Boat Motor Luggage Rack	Motor Bike: Battery Cables Chain Air Filter Tires Luggage Rack: Bolts Petrol: Containers	Motor Bike: Brake/Clutch Adjustment Valve Tappets Plugs and Points Lantern Boat Motor Kerosene Stove Hand Winch (Lubricate) Mosquito Bar/Net Refrigerator: Door Gasket Defrost

DAILY AND WEEKLY TRUCK INSPECTION CHECKLISTS

Daily	Weekly
Tires	Tires
	Radiator
Radiator	Battery
	Oil:
Battery	Level
	Leaks
Oil Pressure	Petrol:
	Leaks
Oil Level	Hydraulic Fluid Level
	Air Filter
Petrol	Exhaust Heat Riser
	0il Pressure
Alternator	Alternator

QUARTERLY INVENTORY REPORT

4. Inver	ntory Performed By:				
5. Items	TRUCK PARTS				
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NUMBER	DESCRIPTION	OTR BAT	L RECEIVED	ISSUED	BALANCE
3000010	Alternator, 59 Amp			-	-
2226906 2226905	Arm. Wiper. Left			-	
2444611	Arm. Wiper. Right Battery, 70 Amp/hrs.		STATE OF THE PARTY		-
1799378	Bearing, Clutch, Assembly		San Annual Control		
1667008	Bearing, Cone, Differential Pinion, Ft.	80 000	All California Co.		
1799300	Bearing, Cone, Differential Pinion, Ft.				
1799296	Bearing Cone, Differential Side				
1937771	Bearing, Cone, Inner Front Axle				
1790546	Bearing, Cone, Outer Front Axle				
1799299	Bearing, Cup, Differential Pinion, Ft.	ETICK ALL			
1327847	Bearing, Cup, Differential Pinion, Rr.				
1799295	Bearing, Cup, Differential Side				TEL TO
1937770	Bearing, Cup, Inner Front Axle	THE SAME OF			
1139293	Bearing, Cup, Outer Front Axle				
2240368	Bearing, Main, Pkg. #1 Std.				
2240372	Bearing, Main, Pkg. #3 Std.				
2240376	Bearing, Main, Pkg, #2-4 Std.			-	
2421356	Bearing, Rod, Pkg (4 Sets)				
2098986	Bearing, Starter, Pinion HSG				-
2098478	Bearing, Alternator, Front		-		-
2098512	Bearing, Alternator, Rear			-	-
132976 1889129	Belt, Fan Bendix, Starter			-	-
1924763	Blade, Fan				-
2196332	Blade, Wiper		THE RESERVE		-
2508956	Brake, Shoe, W/Lining Front-Front			1588	
2508956	Brake, Shoe, W/Lining Front-Rear				
2508957	Brake, Shoe, W/Lining Rear-Front		Ma West State		
2508957	Brake, Shoe, W/Lining Rear-Rear				
2084673	Brush, Alternator, Set	RAPES I			
2525529	Brush, Set, Starter				
151577	Bulb, Dome light				
9418772	Bulb, Parking and Tail light				
2421199	Cable, Battery to ground				
2421199	Cable, Battery to Relay				
2495510	Cable, Ignition (plug) Set				
	Cable, Parking Brake		-	-	-
2084070	Cable, Relay to Starter				-
2098765	Cap, Distributor				
1373136	Cap, Filler		-	100-100-	-
1782980	Cap, Fuel Tank Capacitor, Alternator		SUB-RESIDENCE		-
2495972	Carburetor		NEW TOWN		
2299030	Carburetor, Repair Kit		E 9 ENTACE SE		
274461	Clamp, Hose	TARREST AND	The second second		
2495531	Coil, Ignition				

	Demant Demind
Country	Report Period

	PARTS (CONT'D)	a.	b.	C.	d.
PART		PREVIOUS	A CONTRACTOR OF THE PARTY OF TH		1.2
NUMBER	DESCRIPTION	OTR BAL	RECEIVED	ISSUED	BALANCI
098058	Condenser. Distributor				
084091	Contact & Gasket. Solenoid. Starter				
2099844	Contact. Distributor. Set				
889151	Core. Solenoid. Starter				
787876	Cover and Pressure plate, Clutch				
268442	Crankshaft		44		
752683	Cylinder, Brake, Repair Kit, Ft.				
2448344	Cylinder, Brake, Repair Kit, Master		10.20		
7552683	Cylinder, Brake, Repair Kit, Rear				
933465	Disc. Clutch. W/Facing				
921758	Drum, Brake, Front		200		
1921761	Drum. Brake. Rear	A SHELL BY			
2098869	Electrolyte, Battery				
2532635	Engine, 225 LC				
1791960	Felt				
2532752	Filter, Oil, Cartridge				
1927343	Fork. Release. Clutch	THE WARRE			
148369	Fuse, 6 Amp. Alternator			1000	
121114	Fuse, 30 Amp, Horn				
145511	Fuse, 2 Amp, Lamp				
120151	Fuse, 15 Amp, Turn Signal				
1922318	Gasket, Axle Shaft Flange				
2585200	Gasket, Engine, Set	THE COMPANY			
1789889	Gasket for Flange		230670		The same of
2511471			VEU II STERRE		
2585201					
1791957				-	
1922306_					
1791895	Gear & Pinion 4.09:1		-	-	
		510 ST 1510 ST	100 00 000 000	1	
1673646	Gear, Ring, Flywheel		1	1	_
1889363	Head, W/bearing, starter Hose, Brake, Front (2)		1 1 1 1 1 1 1		_
1261958			-	-	-
581545	Hose, Brake, Rear (1)		-	+	-
1739230	Hose, Fuel Hose, Radiator, Lower	-	-	+	+
2084044_		_	-	-	-
1881804	Hose, Radiator, Upper	-	-	-	-
2298908	Joint, Universal, Front		THE RESIDENCE	1 5 5 6 6	+
1881657	Joint, Universal Kit		+	1	-
2298908	Joint, Universal Rear		-	+	1
2505055	Kingpin W/Teflon Bushing		+	+	-
2595071	Lining, Pkg, Front Wheels		-	+	-
2495071		-	1		
1939107			-	-	
1939106			-	+	+
1614666			-	-	
381875	Lock, Intake Retainer		-	-	-
1889100	Motor, Starter		-	+	+
2225575		-	+	-	-
2506865		-	-	-	-
2515600			+	-	-
2515601	Nut, Lt, Hub, Stud	-	-	-	-
2228251	Pipe, Tail, (WB 146")				1

Country___

Report Period

PART	PARTS (CONT'D)	a. PREVIOUS		c.	d.
NUMBER	DESCRIPTION	QTR BAL	RECEIVED	ISSUED	BALANC
2084388	Piston, W/Pin, Std				
2098336	Plug, Spark				
2495526	Pump, Fuel	1			
2196910	Pump, Water				
2298907	Pump, Water, Repair Kit				
2235125	Radiator, Core			- metales Aures	O MEDICE
	Rectifiers Diode, Negative	HA THE REAL PROPERTY.			
	Rectifiers Diode, Positive				
3000074	Regulator, Voltage				
	Resistor, Ballast				
2448735	Ring, Piston, Std, .009, Set	S LINE TO LAND		25 102 12	
2406657	Rod, Connecting, Assembly			10 mg at 1	
2098770	Rotor, Distributor				
1791590	Seal, Oil				
1795192	Seal, Oil Differential Pinion Brg				
1791591	Seal, Oil, Pinion			10 10 A 20 E T	
2084411	Seal, Oil, Rear Main Bearing, PKG			DIESTE PROBLEM	
1791963	Seal, Oil, Univ. Drive Shaft			Maria Control	
2512675	Shaft, Drive	III and the state	St. Dall Co.	1486	
	Shaft, Drive, Rear, 4 Whl. Drive				
	Shaft Drive, Trans. to Transfer Case	THE NAME OF			
2240349	Shock Absorber, Front			January State	
2240348	Shock Absorber, Rear	S POWER TO	ENTRY NAMED IN		
1889146	Solenoid, Starter			Variation of	
1733934	Spring, Exhaust Valve				
2237058	Spring, Front, 1500 lbs.	ne ne el sur y	Marie Print	11703	
1939457	Spring, Front, 1550 lbs.				
1739534	Spring, Intake Valve				
1938152	Spring, Rear 3125 W/Aux.				
1664538	Spring, Return, Front		HET - TIRE OF		
1664538	Spring, Return, Rear		E TOTAL		
1921763	Stud, Hub, Lt (16)		Control -		
1921762	Stud, Hub, Rt (16)				
	Tie Rod - 2 Wh				
	Tie Rod - 4 Wh				
1879443	Tie Rod, End, PKG				
1311175	Tie Rod, End, PKG		CONTAINING BY		
	Transfer Case	di falluerate di	Date of the		
	Transfer Case, Rebuild Kit				ALK TO
2513842	Transmission (435 Synchromesh)				
2508064	Tube, Prop Shaft, Front				
2227510	Tube, Prop Shaft, Rear				
1947624	Valve, Exhaust				
1947623	Valve, Intake				
2226125	Worm, Steering, LHD, Assembly				
2226140	Worm, Steering, RHD, Assembly	district on and	C 1972 Y 15 Y		
CHUSTI III					
03088	A STATE OF THE STA			onlife a 10	

Country	Report Period	

5. Items (Cont'd)

B. JET INJECTOR PARTS

		a.	b.	c.	d.
PART		PREVIOUS		AB DBCC	
NUMBER	DESCRIPTION	QTR BAL	RECEIVED	ISSUED	BALANCE
J-87	Balls, 3/16", Nylon				
J-88	Balls, 3/32", Nylon				
J-89	Balls, Stainless, 3/16"				
116 & 117	Envelopes, 10 each of wire, cloth		PEARING		
J-44-6834A	Feedneedle, Kit				
J-3950-55	Holder, Bottle	S THE PARTY NAMED IN			
	Lubricant, Tube		The state of the s		
16	Pin, Firing			1086	Hall
J-23	Piston, Injection		Legis Library		
J-90	Piston w/seal (90)				
J-97	Piston, ring (97)				
J-33-629	Pump, Vaccine, SS Cylinder	E III SV. III III I	LEON COM		
J-93	Seal, "O" Ring, Size 1				
J-90	Seal, Quad, Size 5				
J-92	Seal, Quad, Size 15				
J-91	Seal, Quad, Size 8	in similar to	To Manage	I Ken Wee	
J-95	Seal, "O" Ring, Size 8		Manual Control	NAME OF STREET	
J-94	Seal, "O" Ring, Size 5	Th 1 40 (1)			
J-96	Seal, "O" Ring, Size 5, Teflon	LINE VENEZIONE		THE OWNER	
J-85	Spring, Main Firing			JUED WAL	
J-97	Ring, Back Up, Size 5		I I I Darring		
84A	Screen, Feedneedle		Partition and		
J-40	Spring, Helical, Outlet Valve			BASE NO. 15	
J-20	Trigger, Firing				
	Tube, Teflon Air Filter				
J-31-2	Valve, Outlet		I MERLY PIEU		
		10 to 12 and 10		MANAGE	
				1	
				Marie No.	
			100 450		
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C. VACCINE AND DILUENT VIALS

		a.	b.	c.	d.
TYPE	DESCRIPTION	PREVIOUS VTR BAL	RECEIVED	ISSUED	BALANCE
Smallpox .	Jet Injector - 100 Dose Vials				
Smallpox	Jet Injector - 500 Dose Vials				
Smallpox	Multiple Pressure - 100 Dose Vials				
Measles	Jet Injector - 50 Dose Vials				
Diluent	25 c.c. Vials				

Country	Report Period
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5. Items (Cont'd)
D. MISCELLANEOUS (Motor Bike; Outboard Motor, etc.)

		8.	b.	c.	d.
PART	The second secon	PREVIOUS	THE STATE OF THE STATE OF		
NUMBER	DESCRIPTION	QTR BAL	RECEIVED	ISSUED	BALANCE
THE PROPERTY					
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	OF THE OWNER OF STREET, STREET		ALC: VALUE OF		
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	The second secon				
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			-		-
			THE PARTY		
					In Lea
			1, 91, 191, 191, 1		
				Manual Co.	
	The second secon	CONTRACTOR SERVICE			
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		and the control person	resist and a		-
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DA BACTERIA			mental services		
	A PROPERTY OF A		Children -		
			EL MANAGEM		
		Charles and Constitution	Madellaceurante		
PARTY AND A	TO REPORT OF THE PARTY OF THE PARTY.				-
			CHEST OFFICE		
			-	-	
TO SERVE SITE		NOT THE OWNER OF THE	-		
			2002 20000	-	
			-	-	
				-	
			-	-	
			The state of the state of		

INSTRUCTIONS FOR PREPARING THE QUARTERLY INVENTORY REPORT

- 1. Country Enter the name of the country for which this inventory was performed.
- 2. Date of Inventory Report Enter the actual date the inventory was performed.
- 3. <u>Inventory Report Period</u> Enter the period of time, in months and year, that is covered by this report. (e.g., January, February, March, 1967)
- 4. Inventory Performed By Enter the name and title of the person who performed this inventory.

5. Items -

A. Truck Parts and B. Jet Injector Parts

Column a - Enter the previous quarter balance of each part listed. These figures must equal the totals in column d on the previous Quarterly Inventory Report.

 $\underline{\text{Column } b}$ - For each part listed enter the quantity received during this quarterly report period.

Column c - For each part listed enter the quantity issued during this quarterly report period.

Column d - For each part listed enter the balance on hand at the end of this quarterly report period. Balances in column d will be carried forward to appropriate spaces in column a of the next Quarterly Inventory Report.

C. Vaccine and Diluent

Column a - Enter the number of vials on hand at the first of this quarterly report period. These totals must equal the appropriate totals in column d on the previous Quarterly Inventory Report.

Column b - Enter the number of vials received during this quarterly report period.

Column c - Enter the number of vials issued during this quarterly report period.

Column d - Enter the number of vials on hand at the end of this quarterly report period. Balances in column d must equal appropriate balances of column a plus column b minus column c. Balances in column d will be carried forward to appropriate spaces in column a of the next Quarterly Inventory Report.

D. Miscellaneous (Motor Bike, Outboard Motor, etc.)

<u>Part Number</u> and <u>Description</u> - Enter the part number and the description in the appropriate columns for each part in the miscellaneous category. Omit items in the field equipment category.

Use the same instructions for filling out columns a, b, c, and d as those given above for Truck Parts and Jet Injector Parts.

MONTHLY REPORT OF ITEMS USED

	1. Country:	2. Report Month:	4. Report Submitte	ed By:
		3. Date of Report:	Name:	
v.c.waj	less ave email had	J. Date of Report.	Title:	a r yange) . t
	5. TRUCK PARTS	<u>Quantity</u>	Description	Part Number
	bassicities of an area	Take and title of the pe	782 78988 - 30 8523	BIA TARRETT
		b .glltoaup Padina scoulto	and a set outside that	
	backless fie no	Day Early Jack Colored	perior to provide	Int special contract
	and to broadly with	n the column marked quan	Dissiplified - arrest -	Constant and A
	less Ifa no lissu.	sing to replacement purit	inited mellowater.	reduct byen
	has notherwest	validanup i silvani anauloo		
	b banakasa fia no i	PARTS	2036282 180 800 38 820	LEL CONTROL
	6. JET INJECTOR F	ARIS		
			A - Swart pow Years	
		ns, Milliple Bressite	C - Manales Vaccin	
			Jasuisa - a	
		s seals and salend no all		2009
	(Motor Bike;			
	Outboard Motor	e, etc.)		
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	Readill on pareuro a	bel fran ed (like 5 fem (or Liver & filmon ras	70 A 000200 EL 8001	
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	8. VACCINE	a. b.	c. 1	d. e.
	Han	als on Vials and at Received of Month During Month	Used Har	als on Vials Neede For Next of Month 3 Months
	SMALLPOX			
	A. JET			
	B. M.P.			
	C. MEASLES			
E EST	D DITHENT	Part of the part o	THE RESERVE OF THE PERSON OF T	

INSTRUCTIONS

MONTHLY REPORT OF ITEMS USED

- 1. Country Enter the name of the country to which the listed items are assigned.
- 2. Report Month Enter the month for which this report was prepared.
- 3. Date of Report Enter the actual date this report was completed.
- 4. Report Submitted By Enter the name and title of the person who submitted this report.
- 5. Truck Parts Indicate in the columns marked quantity, description, and part number, information pertaining to replacement parts used on all assigned trucks during the report month.
- 6. <u>Jet Injector Parts</u> Indicate in the columns marked quantity, description, and part number, information pertaining to replacement parts used on all assigned jet injectors during the report month.
- 7. <u>Miscellaneous</u> Indicate in the columns marked quantity, description, and part number, information pertaining to replacement parts used on all assigned miscellaneous equipment (e.g. motor bikes, outboard motors, etc.).
- 8. Vaccine and Diluent -
 - A Smallpox Vaccine, Jet Injector
 - B Smallpox Vaccine, Multiple Pressure
 - C Measles Vaccine
 - D Diluent
 - ABCDa Enter the number of vials on hand at the first of this report month.

 These totals must equal the appropriate totals in column d on the previous month's Monthly Report of Items Used.
 - ABCDb Enter the number of vials received during the report month.
 - ABCDc Enter the number of vials used during the report month.
 - ABCDd Enter the number of vials on hand at the end of the report month. Balances in column d must equal appropriate balances of column a plus column b minus column c. Balances in column d will be carried forward to appropriate spaces in column a of next month's report.
 - ABCDe Enter the number of vials of smallpox and measles vaccine, and diluent, needed for the next three months.

INSTRUCTIONS FOR PREPARING VEHICLE BREAKDOWN REPORT

- 1. Serial Number Enter the serial number of the truck.
- 2. Odometer Reading Enter the mileage on the truck as indicated on the truck odometer at the time of the breakdown.
- 3. Driver Enter the name of the driver who is permanently assigned to the truck.
- 4. Type of Breakdown Describe the type of breakdown (i.e., electrical failure, flat tire, broken axle, etc.).
- 5. Date and Place of Breakdown Indicate the date and location of this breakdown.
- 6. Date Returned to Service Enter the actual date the truck was again ready for field operations.
- 7. Date of Last Preventive Maintenance Enter the date when the last preventive maintenance was performed (e.g. lubrication, oil change, repairs, etc.).
- 8. Parts Used Indicate the quantity, description, and part number of all replacement parts that were used to repair this turck in connection with this particular breakdown.
- 9. Name of Service Facility Enter the name of the service facility that performed the repairs on this particular breakdown.
- 10. Repairs Performed By Enter the name of the person who actually performed the repairs.
- 11. Remarks Include the probable cause and corrective action relating to this vehicle breakdown. Indicate the type of terrain and climatic conditions of the area in which the breakdown occurred.
- 12. Month Reported to R.P.O. Enter the month that this vehicle break-down was reported to the Regional Project Office.
- 13. Report Prepared By Enter the name of the person who prepared this report (e.g. operations officer, driver, team leader, etc.).

VEHICLE BREAKDOWN REPORT

1.	Serial Number:	2. Odometer	Reading: 3.	Driver:	of 16
4.	Type of Breakdown:	5. Date and of Breakd	arrangement and the second	Date Returned to Service:	Preventive
8.	Parts Used: Oty. Desc	The state of the s	art No.	Name of Service	
	dmuő drag oga "mölsk o n. Rossassini szak		4FA - \$47 5 5 502	Repairs Performe:	med By:
11.				Andired to su This profession of	ulo"
12.	Month Reported to R.	.P.O.:	13. Report Pr	epared By:	

INSTRUCTIONS FOR PERFORMING MONTHLY TRUCK INSPECTIONS

The inspection points listed below are vital to the operating efficiency of the vehicle. Every effort should be made to see that <u>all</u> inspection points are in satisfactory condition when the inspection is completed. The letters and numbers in parentheses following the items listed below (e.g., SM 23-4), refer to the section and page number of the <u>Dodge Truck Service Manual</u> where corrective procedures are shown and/or discussed.

OUTSIDE TRUCK INSPECTION

Doors: Check to see that doors open and close properly. Is there sufficient grease on door strikers and latches? (SM 23-4)

Windows: Check for cracks, breaks, and leaks. Make certain that window mechanism operates freely. (SM 23-10)

Bumpers: See that bolts and tow hook are tight.

Headlamps: Check mounting of lamps for tightness and that lamps are not broken or bulb burned out. (SM 8-87)

Tail lamps: Check mounting of rear lamps. See that reflectors are clean and bulbs not broken or burned out. (SM 8-88)

Turn
signals: See that lights operate properly in both directions. (SM 8-88)

Side view mirror: Check the mounting bracket and see that the glass is not cracked or broken. Replace if necessary.

<u>wipers</u>: Check the condition of rubber blade. Make certain that no metal scrapes on the windshield. (SM 8-82)

Spare tire: Check tires for recommended inflation. See that mounting bracket is secure and that locks are in place. (SM 22-1)

Luggage
rack: See that rack and mountings are secure. Are rubber gaskets in proper condition to avoid leaks?

UNDER HOOD INSPECTION

Hood: See that the hood closes tight and easily, and that the latch is lubricated. Latch should operate properly without binding. (SM 23-3) See that the hinge mechanism operates smoothly without binding and that the mounting screws are tight. (SM 23-3)

Radiator: Check for correct water level. Water should be clean and not rusty. Be certain hoses are not cracked. Check hose connections for leaks.

(SM 7-3)

Fan belt: See that the belt is not frayed and that it is properly adjusted. Replace if necessary.

Battery: Be sure water is at proper level. Make certain posts are clean and free of corrosion. Battery cable connections must be tight and lubricated. (SM 8-1)

Oil: Check oil level dip stick for proper oil level and whether oil is clean. See that oil filter is not leaking. Tighten if needed. (SM 0-8) Are there any oil leaks around engine gaskets? (SM 9-7)

Fuel filter: See that line filter is clean and free of water. (SM 14-1)

Carburetor: Check for fuel leaks and proper throttle linkage. (SM 14-0)

Air cleaner: Check oil level. Make certain oil is clean. (SM 0-11)

Clutch master

Check hydraulic fluid level. Make sure that fluid is not leaking from cylinder: cylinder. (SM 6-5)

Brake master

Check hydraulic fluid level and see that fluid is not leaking from cylinder: cylinder. (SM 5-9)

Water pump: Check the bearing for squealing sounds. Lubricate or replace if necessary. Check the bearing and seals for leaks. (SM 7-4)

Crankcase

vent valve: Check for a clogged line or inoperative valve. (SM 0-10)

Crankcase breather

cap:

See that cap is clean and that oil blowback is not occurring. (SM 0-11)

heat valve: Make certain valve moves freely and that it is well lubricated. (SM 11-5)

Steering

gear box: Be sure that lubricant is at proper level. Check seals for leaks. (SM 0-15)

Motor

mounts: Check for broken or loose mounts. Tighten or replace as needed.

Distributor

Check for corroded connections. Check cap for cracks. Check inside of

the cap for wear at the rotor connection. (SM 8-52)

Distributor

Check spring connection for any wear or corrosion. Make certain wiper rotor:

connection is smooth and free of corrosion. (SM 8-52)

Points: Make sure that points are clean and that the gap is correct. (SM 8-52)

Plugs and

Make certain plugs are clean and that the gap is correct. Check for wires:

cracks in porcelain. Check wires for cracks or bad insulation. Check resistance of wires. (SM 8-72)

Voltage Be sure that voltage across battery with engine running is 14.2 volts. output:

(SM 8-1)

Valves Check the sound of valves with the engine running. Remove valve cover timing:

and adjust valve tappets if necessary. (SM 9-1)

Bearing Listen to engine while it is running. Any bearing knocks or grinding knocks:

sounds? (SM 9-1)

UNDER TRUCK INSPECTION

Tires: Check tires for recommended inflation and even wear. (SM 22-1)

Front
wheels:
Rotate wheels to check bearings. Check each wheel bearing by shaking wheel parallel to axle. Check lubricant level. (SM 2-16) Make

certain hub seals are not leaking. (SM 2-16)

Shock
absorbers: See that mountings are not worn or loose. (SM 17-1)

Springs: Check for broken leaves. Make certain that connections on each end are

tight. Check the rubber grommets for wear. (SM 17-1)

Radius rod: Check for bearing wear and if rod is bent.

Steering

arm: Check for bearing wear and adjustment. (SM 2-10)

Emergency

brake cable: Check for frayed cable or excess slack. (SM 4-5)

Oil pump: Check for leaking seals. (SM 10-2)

Oil filter: Check for leaks. (SM 9-106)

Clutch slave

cylinder: Check seals for leaking hydraulic fluid and clutch arm linkage. Replace

if leaking.

Fuel pump: Check for leaks. (SM 14-47)

Fuel tank: Check for leaks. Make sure mounting brackets are tight. (SM 14-50)

Fuel lines: Check for leaks. Make certain lines are not crimped. Are line

positioning clamps in place? (SM 14-50)

Differential

drive case: Check front and rear lubricant levels. Make sure there are no seal

leaks. (SM 2-18, 3-16)

Universal

joints: Check universals to make certain there is no bearing wear or excessive

play. Check bearing seals. (SM 16-1)

Transfer

case: Check seals for leaks. Check lubricant level. Check shift linkage for

wear. (SM 21-56)

Transmission: Check seals for leaks. Check shift linkage for wear. Check lubricant

level. (SM 21-22)

Welch plugs: Check for rust or leakage of water. Rust around the edges of the plug

openings indicates a seepage leak and the plugs should be replaced.

Wiring

harness: Check the wiring going to auxillary equipment to make certain it is not

frayed or that insulation is broken. See that wiring clamps are in

position.

Muffler: Check muffler and tail pipe for holes. Make sure mounting clamps are

tight.

Take a general look at underside of truck to make certain nothing is Loose bolts:

leose or out of place.

Frame and

Check for any damage and condition in general. body:

INSIDE CAB INSPECTION

Steering

Check for excessive play in the wheel. Check for bearing wear. (SM 19-1) wheel:

Sound horn. (SM 8-86) Horn:

Turn signal

Check for excessive play. (SM 8-88) lever:

Rear view

mirror: Make certain mounting is tight.

See that mountings are tight. Sunvisors:

Gear shift

Check for excessive travel. With engine running, check ease of meshing lever:

gears. (SM 21-15)

Clutch

Check length of travel. Check wear of tread pad. (SM 6-1) pedal:

Check length of travel. Check wear of tread pad. (SM 5-2) Brake pedal:

Cab

Check for signs of water leakage. (SM 23-10) tightness:

Seats and

Check for tightness of mountings. Check belts for frayed webbing. belts:

See that indicator is working. (SM 8-75) indicator:

Heat

See that radiator is working and indicating normal temperature. (SM 8-75) indicator:

INSTRUCTIONS FOR PREPARING MONTHLY TRUCK INSPECTION REPORT

- 1. Serial number Enter the serial number of the truck.
- 2. Driver Enter the name of driver permanently assigned to this truck.
- 3. Date of inspection Enter actual date that truck was inspected.
- 4. Country Enter the name of country to which truck is assigned and used. Indicate region of country if applicable.
- 5. Odometer reading Enter the total mileage of truck at the time of inspection as indicated on odometer.
- 6. Total miles for month Enter total mileage travelled since the odometer reading as stated on the previous month's Monthly Truck Inspection Report.
- 7. Total gasoline used Enter the total amount of gasoline issued to the truck since the odometer reading shown on the previous month's report. Specify litres or imperial gallons.
- 8. Number of breakdowns Enter the total number of times the truck became inoperative and had to have repairs or service before resuming operation.
- 9. Total down time in hours Indicate actual continuing hours the truck is out of operating condition.
- 10. Parts used List the quantity of each replacement part used during the inspection.

 Indicate the exact inventory description and part number.
- 11. Date of last preventive maintenance Enter the date when the last preventive maintenance was performed (e.g. lubrication, oil change, repairs, etc.)
- 12. Facility performing last preventive maintenance Enter the name and address of facility which performed the last preventive maintenance.
- 13. Facility performing this inspection If the preventive maintenance was done by some facility, list the name and address.
- 14. Person performing this inspection Enter the name and title of individual who made this inspection.
- 15. Check the items listed indicating satisfactory or unsatisfactory conditions after the inspection. Explain in Remarks Section why the unsatisfactory items were not corrected. Items should be inspected in accordance with procedures and specifications as outlined in the Dodge Truck Service Manual and the Operations Officer's Manual.
- 16. Remarks should always include any comments or suggestions felt to be pertinent for improved vehicle operation. Helpful hints are always important.
- 17. Enter the month covered by this report.
- 18. Enter the name and title of person submitting this Monthly Truck Inspection Report.

MONTHLY TRUCK INSPECTION REPORT

. Ser	ial Nu	mber: 2. Driver	(T) 1	di e	3. Date of Inspection		4. Cour	ntry:	15 11
	ometer ading:	6. Total for M		194 (J	7. Total Amt. Gas for Mo		8. No. Brea	of akdowns	9. Total Down Time in Hours:
Qty.	nes	Agreement Religion	art Nu	mber	11. Date of La Preventive Maintenance	2	Las	cility P st Preve intenanc	
	1 10 10 10 10 10 10 10 10 10 10 10 10 10	COLUMN TO SERVICE			13. Facility 1		ming to		ection:
		No a contact to a	seq lim	10.7	14. Person Pe	ELLOID	arng th	rs rusbe	ection:
t	his in	he items below i spection. Expla rected.			Name: atisfactory or ks Section why				
t n	his in	spection. Expla			atisfactory or ks Section why	the i		factory	
t n	his in	spection. Expla	in in		atisfactory or ks Section why UNDER	the i	INS PEC	factory	
outs I	his in ot cor	spection. Expla	in in	Un-sat.	atisfactory or ks Section why UNDER	HOOD	INSPEC	Clutch Brake of Water Cranker Cranker Manifo Steeri Motor Distri Cap Roto Points Plugs	master cyl. master cyl. pump ase vent valv ase breather ld heat valve ng gear box mounts butor r and plug wire e output

Sat.	Un- sat.		Sat.	Un- sat.	
		Tires	()	()	Clutch slave cylinder
()	()	Inflation	()	()	Fuel pump
()	()	Wear	()	()	Fuel tank
		Front wheels	()	()	Fuel lines
()	()	Hubs	()	()	Differential drive case
()	()	Bearings	()	()	Universal joints
()	()	Seals	()	()	Transfer case
()	()	Shock absorbers	()	()	Transmission
()	()	Springs	()	()	Welch plugs
()	()	Radius rod	()	()	Wiring harness
()	()	Steering arm	()	()	
()	()	Emergency brake cable	()	()	Loose bolts
()	()	Oil pump	()	()	Frame and body
()	()	Oil filter			
		INSIDE C	AB INSPECTI	ON	
	Un-			Un-	
Sat.	sat.		Sat.	sat.	
()	()	Steering wheel	()	()	Clutch pedal
()	()	Horn	()	()	Brake pedal
	()	Turn signal lever	()	()	
()	()	Rear view mirror	()	()	Fuel indicator
()	()	Sun visors	()	()	Oil pressure indicator
()	()	Gear shift lever	()	()	Heat indicator
16. <u>F</u>	REMARKS				
			× 100		

Memorandum

TO : Field Staff, Smallpox Eradication Program

DATE: November 2, 1966

FROM

Chief, Smallpox Eradication Program

SUBJECT:

Sterilization of Jet Injectors (For insertion on inside front cover of manual)

Sterilization of jet injection equipment can be accomplished by autoclaving at 121 degrees centigrade for 20 minutes. Boiling for 25 minutes has been employed, but this does not assure the killing of all spores. To assure sterilization by either of the above methods, reassembly of the jet injector in an aseptic manner is required. In field operation in West Africa reassembly in an aseptic manner, especially in dry dusty areas has proven difficult. Therefore studies were undertaken at the Communicable Disease Center to develop an acceptable method of cold sterilization applicable to field operations in West Africa. The following appears to be the simplest and most effective method for sterilization of the gun after disassembly:

- 1. Scrub disassembled parts with a scrub brush in a pan of soapy (bar soap) water. Flush with a 20 cc. syringe (adapted with 1/4 inch rubber tubing) the L-shaped tube which extends from the inlet valve to the vaccine chamber and also the needle.
- 2. Rinse parts in a second container of clean water.
- 3. Reassemble injector and prime with 2 percent tincture of iodine.
- 4. Fire three 0.5 cc. shots.
- Fill chamber with tincture of iodine solution (gun in cocked position) and leave for 5 minutes.
- 6. Flush with 10 0.5 cc. shots of sterile water.

This process for sterilization was tested by contaminating four injector with dirt containing 20,000 aerobic and anaerobic organisms per gram (dirt treated so that spores were present). With this degree of contamination, no growth was obtained from any of the guns.

n.b.: With extensive contamination with dirt, further cleaning of ball valves, rings and seals was required to prevent particulate clogging of orifice.

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Memorandum

DEPARTMENT OF HEALTH, EDUCATION, AND WELFAR
PUBLIC HEALTH SERVICE

TO : Holders of the Manual

DATE: May 31, 1967

FROM

Chief, Smallpox Eradication Program

SUBJECT :

Sterilization of Jet Injectors

Recent studies conducted by John Noble in the Vesicular Disease Laboratory, NCDC, demonstrate that the sterilization method advocated in the field staff memorandum of November 2, 1966 does not provide sufficient flushing to prevent a deleterious effect of residual iodine on measles vaccine potency.

A summary of the results were forwarded to each field post. These data indicate that sufficient residual iodine remains after the recommended flush procedure to deleteriously affect at least the first five doses of measles vaccine administered after the iodine sterilization procedure. The 20th dose following the procedure was found to be without evidence of residual iodine effect.

In view of this, the following amendment should be made to the memorandum of November 2.

Under point 6 - "Flush with 10 0.5 cc. shots of sterile water" should be changed to read "Flush with 30 0.5 cc. shots of sterile water."

This change is interim until additional studies in the laboratory have defined the minimum number of flush doses required to assure an absence of residual iodine effect.

Consonant with this change in sterilization practice should be a re-emphasis of the desirability of using heat sterilization techniques where these can be done practicably in the field.

. D. Millar, M.D.

